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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM F-1**  
**REGISTRATION STATEMENT**  
*UNDER*  
*THE SECURITIES ACT OF 1933*

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**Valneva SE**

(Exact name of registrant as specified in its charter)

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**France**  
(State or other jurisdiction of  
incorporation or organization)

**2836**  
(Primary Standard Industrial  
Classification Code Number)

**Not Applicable**  
(I.R.S. Employer  
Identification Number)

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**Valneva SE**  
**6 rue Alain Bombard**  
**44800 Saint-Herblain, France**  
**+33 2 28 07 37 10**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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**Valneva USA, Inc.**  
**910 Clopper Road, Suite 160S**  
**Gaithersburg, MD 20878**  
**+ 1 301 556 4500**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act.

Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards<sup>†</sup> provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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#### Calculation of Registration Fee

Title of Each Class of Securities to be Registered(1)(2)(3)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee(4)
Ordinary shares, €0.15 nominal value per share	\$	\$

- (1) All ordinary shares in the U.S. offering will be in the form of American Depositary Shares, or ADSs, with each ADS representing ordinary shares. ADSs issuable upon deposit of the ordinary shares registered hereby are being registered pursuant to a separate registration statement on Form F-6.
- (2) Includes ordinary shares, which may be in the form of ADSs, which the underwriters have an option to purchase. See "Underwriting."
- (3) Includes ordinary shares that are being offered in the European offering, but which may be resold from time to time in the United States in transactions requiring registration under the Securities Act or an exemption therefrom.
- (4) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum offering price.

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**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

<sup>†</sup> The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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### **Explanatory Note**

The Registrant has prepared this Amendment No. 3 (this “Amendment No. 3”) to its draft registration statement on Form F-1, as amended, as most recently submitted with the Securities and Exchange Commission on March 24, 2021 (the “Draft Registration Statement”), solely for the purpose of filing or refiling certain exhibits and making corresponding updates to Item 8 of the Draft Registration Statement. This Amendment No. 3 does not modify any provision of the preliminary prospectus that forms Part I of the Draft Registration Statement and, accordingly, such preliminary prospectus has not been included herein.

**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**ITEM 6. Indemnification of Members of the Management and Supervisory Board.**

Under French law, provisions of bylaws that limit the liability of directors are prohibited. However, French law allows *société européenne* to contract for and maintain liability insurance against civil liabilities incurred by any of their directors and officers involved in a third-party action, provided that they acted in good faith and within their capacities as directors or officers of the company. Criminal liability cannot be indemnified under French law, whether directly by the company or through liability insurance.

We maintain liability insurance for the members of our Supervisory Board and Management Board, including insurance against liability under the Securities Act of 1933, as amended, and we intend to enter into agreements with the members of our Supervisory Board and Management Board to provide contractual indemnification. With certain exceptions and subject to limitations on indemnification under French law, these agreements will provide for indemnification for damages and expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity.

Certain of the members of our Supervisory Board may, through their relationships with their employers or partnerships, be insured and/or indemnified against certain liabilities in their capacity as members of our Supervisory Board.

In any underwriting agreement we enter into in connection with the sale of ADSs being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

**ITEM 7. Recent Sales of Unregistered Securities.**

Set forth below is information regarding share capital issued since January 1, 2018. None of the transactions described below involved any underwriters, underwriting commissions, or any public offering. Some of the transactions described below involved members of our Supervisory Board and Management Board and 5% shareholders and more are fully described under the section of the prospectus titled "Certain Relationships and Related Party Transactions."

From January 1, 2018 through December 31, 2020, we have issued securities in the following transactions that were not registered under the Securities Act:

- On October 1, 2018, we issued 13,333,334 ordinary shares, in connection with a private placement whose total cash contributions amounted to €50,000,002.50 (including €2,000,000.10 in nominal).
- On May 3, 2019, we issued 3,125 new ordinary shares to a Supervisory Board member, in connection with the exercise of equity warrants on April 24, 2019 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On July 29, 2019, after a four-year vesting period, 19,725 free convertible preferred shares (previously granted to employees and Management Board members) vested. They were included in the share capital through incorporation of issue premiums of 2,958.75 Euros.
- On November 4, 2019, we issued 3,125 new ordinary shares to a former Supervisory Board member, in connection with the exercise of equity warrants on October 25, 2019 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On May 15, 2020, we issued 3,125 new ordinary shares to a former Supervisory Board member, in connection with the exercise of equity warrants on May 12, 2020 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).

- On July 29, 2020, we issued 4,875 new ordinary shares to a Supervisory Board member, in connection with the exercise of equity warrants on July 27, 2020 carried out by cash contribution of €19,110 (including €731.25 as nominal value).
- On August 31, 2020, we issued 3,125 new ordinary shares to a Supervisory Board member, in connection with the exercise of equity warrants on August 25, 2020 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On December 1, 2020, we issued 3,125 new ordinary shares to a former Supervisory Board member, in connection with the exercise of equity warrants on November 26, 2020 carried out by cash contribution of €8,043.75 (including €468.75 as nominal value).
- On December 10, 2020, we issued 12,500 new ordinary shares to former and current Supervisory Board members, in connection with the exercise of equity warrants on December 4, December 7 and December 9, 2020 carried out by a total cash contribution of €32,175 (including €1,875 as nominal value).

The issuances of the securities described above were exempt from registration either (a) under Section 4(a)(2) of the Securities Act in that the transactions were between an issuer and sophisticated investors or members of its senior executive management and did not involve any public offering within the meaning of Section 4(a)(2), (b) under Regulation S promulgated under the Securities Act in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States or (c) under Rule 701 promulgated under the Securities Act in that the transactions were under compensatory benefit plans and contracts relating to compensation.

## ITEM 8. Exhibits and Financial Statement Schedules.

### (a) Exhibits

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Schedule/Form</u>	<u>Incorporated by Reference</u>		
			<u>File Number</u>	<u>Exhibits</u>	<u>Filing Date</u>
1.1*	Form of Underwriting Agreement				
3.1+	Bylaws ( <i>statuts</i> ) of the Registrant (English translation)				
4.1*	Form of Deposit Agreement				
4.2*	Form of American Depositary Receipt (included in Exhibit 4.1)				
5.1*	Opinion of Hogan Lovells Paris LLP				
10.1†+	Research Collaboration and License Agreement, dated April 29, 2020, by and between Pfizer Inc. and Valneva Austria GmbH.				
10.2†	SARS-CoV-2 Vaccine Supply Agreement, dated September 13, 2020, by and among the Secretary of State for Business, Energy and Industrial Strategy, Valneva SE and Valneva Austria GmbH, as amended on December 17, 2020 and January 30, 2021.				
10.3†+	Supply Agreement, dated September 12, 2020, by and between Dynavax Technologies Corporation and Valneva Scotland Ltd.				
10.4†+	Funding Agreement, dated April 1, 2019, by and between Coalition for Epidemic Preparedness Innovations and Valneva SE.				

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Schedule/Form</u>	<u>Incorporated by Reference</u>		
			<u>File Number</u>	<u>Exhibits</u>	<u>Filing Date</u>
10.5†+	Distribution Agreement, dated December 9, 2015, by and between GlaxoSmithKline GmbH & Co. KG and Valneva Austria GmbH.				
10.6†+	Sublicense Agreement, dated April 14, 2003, by and between VaccGen International LLC and Intercell AG, as assigned to the Registrant and as amended.				
10.7†+	Supply Agreement, dated March 1, 2008, by and among Intercell AG, Vetter Pharma-Fertigung GmbH & Co. KG and Intercell Biomedical Ltd., as assigned to the Registrant.				
10.8†+	Contract dated September 9, 2020, by and between the U.S. Defense Logistics Agency and Valneva USA, Inc.				
10.9†+	Credit Agreement, dated February 3, 2020, by and among Valneva Austria GmbH, Valneva SE, Wilmington Trust, National Association and the Lenders, as amended to date.				
21.1+	List of subsidiaries				
23.1*	Consent of Deloitte & Associés				
23.2*	Consent of PricewaterhouseCoopers Audit				
23.3*	Consent of Hogan Lovells Paris LLP (included in Exhibit 5.1)				
24.1*	Power of Attorney (included on signature page)				

+ Previously submitted.

\* To be filed by amendment.

† Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.

#### **(b) Financial Statement Schedules**

All schedules have been omitted because the information required to be set forth therein is not applicable or has been included in the consolidated financial statements and notes thereto.

#### **ITEM 9.Undertakings.**

The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities, other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding, is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless, in the opinion of its counsel, the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question, whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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The undersigned registrant hereby undertakes that:

- (1) for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A, and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Saint-Herblain, France on \_\_\_\_\_, 2021.

**VALNEVA SE**

By: \_\_\_\_\_

Name: Thomas Lingelbach

Title: Chief Executive Officer and President



## POWER OF ATTORNEY

We, the undersigned members of the directors, officers and authorized representative of Valneva SE hereby severally constitute and appoint Thomas Lingelbach and Franck Grimaud, and each of them singly, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this Registration Statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this Registration Statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
_____ Thomas Lingelbach	Chief Executive Officer, President and Chairman of the Management Board (principal executive officer)	, 2021
_____ Frédéric Grimaud	Principal Financial and Accounting Officer	, 2021
_____ Frédéric Grimaud	Chairman of the Supervisory Board	, 2021
_____ James Sulat	Member of the Supervisory Board	, 2021
_____ Anne-Marie Graffin	Member of the Supervisory Board	, 2021
_____ Sharon Tetlow	Member of the Supervisory Board	, 2021
_____ Johanna Willemina Pattenier	Member of the Supervisory Board	, 2021

**Signature of Authorized U.S. Representative of Registrant**

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of Valneva SE has signed this registration statement on the      day of      , 2021.

**Valneva USA, Inc.**

By: \_\_\_\_\_

Name:

Title:

**[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.**

Execution Version

DATED 13th SEPTEMBER 2020

VALNEVA SE

VALNEVA AUSTRIA GMBH

AND

THE SECRETARY OF STATE FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY

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SARS-COV2 VACCINE SUPPLY AGREEMENT

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**THIS AGREEMENT (“Agreement”)** is dated 13th September 2020 and made between:

- (1) **VALNEVA S.E.**, a company registered in France (company number 422,497,560) whose registered address is at 6 rue Alain Bombard 44800 Saint Herblain, France (“**Parent**”); and
- (2) **VALNEVA AUSTRIA GMBH**, a company registered in Austria (company number FN 389960 x /HG Wien) whose registered address is at Campus Vienna Biocenter 3, 1030 Vienna, Austria (“**Valneva**”); and
- (3) **THE SECRETARY OF STATE FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY**, acting on behalf of the Crown, whose principal office is at 1 Victoria Street, London, SW1H 0ET (the “**Authority**”),

(each a “**Party**”, and collectively the “**Parties**”).

## **INTRODUCTION**

- (A) Valneva has discovered and is actively pursuing the clinical development of the Product within the Field in order to file for and secure a Marketing Authorisation for the Product with an indication in the Field that is valid in the Territory, and for its Affiliates to secure equivalent Regulatory Approvals from other Regulatory Authorities for the Product around the world.
- (B) In order to Manufacture sufficient quantities of the Product, Valneva will update, upgrade and validate its existing OB1 manufacturing facilities in Scotland and commits to purchase, update, upgrade and validate additional manufacturing facilities (defined below as OB2) located in close proximity to OB1.
- (C) The Authority, on behalf of the Crown, wishes to [\*\*\*] order and secure [\*\*\*] supplies of the Product, and Valneva wishes to accept such order and supply Product to the Authority in each case in accordance with the terms of this Agreement. The Authority will also be purchasing other Third Party vaccines and other therapeutic products, as part of its national and international strategy towards vaccination against, treatments for, and mitigation of the global impact arising from the spread of SARS-CoV-2.
- (D) Valneva and [\*\*\*] have [\*\*\*] which Valneva will conduct [\*\*\*] in the Territory for the Product, which trials are designed to elicit clinical data to support Valneva’s application for a Marketing Authorisation in the Territory in respect of the Product for an indication in the Field.
- (E) The Authority and the Department for Health and Social Care are willing to provide [\*\*\*] under this Agreement and the [\*\*\*] which Valneva will use to undertake work contemplated by Recital (B) above and in accordance with the [\*\*\*] and in consideration of which, Valneva shall undertake the Development and Manufacturing of the Product for supply in accordance with the terms of this Agreement and [\*\*\*].

**IT IS AGREED that:**

**1. DEFINITIONS**

1.1 In this Agreement, the following words and expressions shall have the following meanings:

“**Additional Order Price per Dose**” has the meaning given in clause 13.6;

“**Adjuvant**” means the adjuvant selected to be incorporated into the Product to be Developed, Manufactured and supplied to the Authority pursuant to the terms of this Agreement;

“**Adjuvant Commitment**” means, at any time during the Term, any and all amounts which Valneva is required and fully committed to pay but has not paid pursuant to any contract with a Third Party for the purchase of Adjuvant in those quantities required for incorporation into the Product to be supplied in accordance with this Agreement;

“**Adjuvant Cost**” means the per Dose cost of any Adjuvant incorporated into the Product to be supplied in accordance with this Agreement;

“**Administering Entity**” means any Health Service Body administering the Product;

“**Affiliate**” means, with respect to (a) Valneva, any Person that Controls, is Controlled by or is under common Control with Valneva from time to time; (b) any Third Party, any Person that Controls, is Controlled by or is under common Control with that Third Party from time to time; and (c) Authority, means any Central Government Body;

“**Applicable Laws**” means applicable laws, rules, orders, bye-laws, instruments, regulations, legislation or similar statutes, ordinances, treaties, directives, administrative interpretations, including Applicable Standards, the Sanctions Guidelines, rules of national stock exchanges and any other rules or regulations promulgated by or otherwise having the force of law of any Governmental Authority or Regulatory Authority in each case in the Territory or any country where activities for or pursuant to this Agreement are undertaken (or, but solely where the context requires, any other relevant geographical area) and/or over a relevant class of persons;

“**Applicable Standards**” shall mean all applicable cGxP requirements and guidelines;

“**Authorised Agent**” means any authorised agent appointed by the Authority as notified to Valneva in writing from time to time;

“**Authority Specific Commitments**” means those land, equipment, goods, services, and other commitments if and to the extent specifically indicated in Schedule 9 as “Authority Specific”;

“**Breaching Party**” has the meaning given in clause 25.4;

“**Business Continuity Event**” means any event or issue that does or could adversely impact the Development, Manufacture or supply of the Product to the Authority in accordance with this Agreement, including, without limitation, the pandemic declared in respect of SARs-CoV-2, any Force Majeure event and the withdrawal of the United Kingdom (or any part of it) from the European Union;

“**Business Continuity Plan**” means Valneva’s business continuity plan, prepared with reasonable skill and care, which includes its plans for continuity of the Development, Manufacture and supply of the Product to the Authority during any Business Continuity Event;

“**Business Day**” means any day that is not a Saturday or Sunday or a public holiday in London, England;

“**Candidate**” means the inactivated whole virus human vaccine candidate known as VAL2001 and described more fully in Schedule 1 and intended for prophylaxis and vaccination against SARS-CoV-2 in humans utilising Valneva’s IXIARO platform technology to be combined with an Adjuvant that may (i) include Dynavax’s CpG 1018 adjuvant; and/or (ii) aluminium hydroxide, with such Adjuvant decision being made in accordance with the Development Plan;

“**Central Government Body**” means a body listed in one of the following sub- categories of the United Kingdom’s Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics: (a) Government Department; (b) Non-Departmental Public Body Assembly Sponsored Public Body (advisory, executive, or tribunal); (c) Non-Ministerial Department; or (d) Executive Agency;

“**cGCP**” or “**GCP**” means current good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of human clinical trials, including those practices described in Directive 2001/20/EC and the Medicines for Human Use (Clinical Trials) Regulations 2004 and the standards required under Directive 2005/28/EC;

“**cGLP**” or “**GLP**” means current good laboratory practices generally accepted within the pharmaceutical industry to promote the quality and integrity of data generated in laboratory testing and to prevent misleading or fraudulent practices, including those practices described in Directive 2004/10/EC and the Good Laboratory Practice Regulations 1999;

“**cGMP**”, “**GMP**” or “**Good Manufacturing Practice**” means the then-current principles and guidelines of good manufacturing practice and general biologics products standards contained in Applicable Laws and guidance including: (a) Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use; (b) Directive 2001/83/EC laying down the principles and guidelines of good manufacturing practice for medicinal products; (c) further guidance as published by the European Commission in Volume 4 (Good Manufacturing Practice) of “The Rules Governing Medicinal Products in the European Union”; and (d) ICH Q7 Guideline “Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, in each case as may be amended from time to time;

“**cGVP**” or “**GVP**” means current principles and guidelines of good pharmacovigilance practice for medicinal products for human use, as set forth in EU Directive 2001/83/EC, Commission Implementing Regulation No 520/2012 and the EMA’s Guideline on Good Pharmacovigilance Practice;



“**cGxP**” or “**GxP**” means cGMP, cGCP, cGLP and cGVP;

[\*\*\*] or [\*\*\*] means the [\*\*\*] governing Valneva’s [\*\*\*] to be undertaken in the Territory for the Product in respect of an indication in the Field, [\*\*\*];

“**Commercially Reasonable Efforts**” means with respect to the efforts, expertise and resources to be expended by a Party with respect to the achievement of an applicable obligation or objective under this Agreement, those diligent, professional and good faith efforts, expertise and resources that are the same as or greater than those normally and customarily used, engaged or otherwise expended or deployed by:

- (a) in the case of Valneva, a professional pharmaceutical company which are objectively and reasonably deployed towards Development, Manufacture and commercialisation of a product for the achievement of the same or a similar objective on a timely basis [\*\*\*] or
- (b) in the case of the Authority, a professionally organised and functioning public authority pursuing the objectives referred to in Recitals [\*\*\*],

in each case having regard to the urgent need for a vaccine to end a global pandemic which is resulting in serious public health issues, restrictions on personal freedoms and economic impact, across the world but taking into account efficacy and safety;

“**Commitment Letter**” means the Commitment Letter entered into between Valneva and the Authority dated [\*\*\*];

“**Confidentiality Agreement**” means the confidentiality agreement entered into between Valneva and the Authority dated [\*\*\*];

“**Confidential Information**” means any business, commercial or technical information (in whatever form or media) of either Party that is confidential or of a confidential nature and which is provided by or on behalf of one Party to the other Party or to which access is obtained (i) prior to the Effective Date, under the Confidentiality Agreement, (ii) on or after the Effective Date, pursuant to this Agreement [\*\*\*], or (iii) as a consequence of entering into or performing this Agreement or [\*\*\*] (in each case whether before, on or after the Effective Date).

Confidential Information includes any information or materials possessed or developed by either Party or their respective Affiliates, whether possessed or developed before, on or after the Effective Date, in relation to the Product and/or services provided hereunder (including know how, processes, techniques, specifications, reports, analyses, sources of supply, marketing plans, sales strategies and pricing information), except for such information that is demonstrably non-confidential in nature. The terms of this Agreement (but not its existence) will be regarded as the Confidential Information of both Parties;

“**Conforming Product**” means Product that has been Manufactured in accordance with and meets the requirements of clauses 5.11 and 5.12;

“**Control**” means: (a) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) to own, directly or indirectly, fifty percent (50%) or more of the outstanding voting securities or other ownership interest of such Person, or (c) in the case of a partnership, control of the general partner, and “**Controls**” and “**Controlled**” shall be construed accordingly;

“**Cost of Follow On Order**” means the aggregate of costs specified in the categories listed at part (c) of the Cost of Product definition below (but excluding (c) (vii), (c) (viii) and (c) (ix) and any other individual items of costs in any other category, which have been taken into account in calculating the Initial Order Price);

“**Cost of Product**” means, to the extent not already reimbursed or committed to be reimbursed by a Third Party, the aggregate reasonable direct costs and expenses incurred by Valneva or any of its [\*\*\*] directly for those Development and Manufacturing activities undertaken pursuant to the Development Plan and Manufacturing Plan and that are necessary for the Development and Manufacture of the Product for the Territory in order to supply units of Product pursuant to this Agreement, which shall comprise the aggregate of:

- (a) Required Commitments;
- (b) [\*\*\*];
- (c) other costs incurred for the Development and Manufacture of the Product (in accordance with the Development and Manufacturing Plans) comprising:
  - (i) direct labour costs (salaries, wages, employee benefits, overtime costs and shift premiums);
  - (ii) direct materials costs (including raw materials and intermediates and interim packaging) but excluding costs for Adjuvant (as referred to in (x) below);
  - (iii) a fair and reasonable allocation of operating costs of the Facilities during Manufacture of the Product, calculated by Valneva in a manner consistent with its treatment of such costs with respect to other products, and without disadvantaging the Product on account of the terms of this Agreement or otherwise;
  - (iv) amounts (without mark-up) that are paid to a Third Party, in connection with their activities for the Manufacture of the Product or any component thereof;
  - (v) research and development costs including the costs for filing and obtaining the Minimum Viable Marketing Authorisation in the Territory and all other costs incurred which are directly attributable to the costs of compiling and filing of the application for the Minimum Viable Marketing Authorisation in the Territory for the Product with an indication in the Field, or any other costs associated with filing and obtaining, or fulfilling the conditions or requirements of, a Marketing Authorisation agreed between the Parties or pursuant to the CTA;

- (vi) to the extent not included in the foregoing categories, a Facility overhead and a reasonable allocation to such supply operation of other overheads without which the Product could not be Developed or Manufactured and the Marketing Authorisation would not have been obtained, calculated by Valneva in a manner consistent with its treatment of such costs with respect to other products, and without disadvantaging the Product on account of the terms of this Agreement or otherwise;
- (vii) capital expenditure and other costs incurred in connection with the acquisition, development or enhancement of OB1 and OB2, to the extent not otherwise included in the above;
- (viii) capital expenditure and other costs incurred in connection with the acquisition, development or enhancement of investments made by Valneva in the Solna Facility for the purposes of the fill-finish of the Product;
- (ix) any UK fees and expenses incurred in connection with the project for the development and manufacturing of the Product, other than in connection with the negotiation and execution or any variation of this Agreement [\*\*\*];
- (x) the Adjuvant Cost; and
- (xi) any non-refundable or non-creditable Indirect Taxes, customs and excise duties, or similar taxes in connection with any of the above,

in all cases to the extent specifically attributable to the Development and Manufacture of those Product units supplied in accordance with the requirements of this Agreement, as applicable, and in each case, calculated by Valneva in a manner consistent with its treatment of such costs with respect to other products, and without disadvantaging the Product on account of the terms of this Agreement or otherwise. For the avoidance of doubt, “**Cost of Product**” excludes each of the following:

- (a) costs related to the operation of any Facility incurred while such Facility is not Manufacturing the Products;
- (b) industrial operations-related and corporate costs which are not directly related to the Product (such as, but not limited to, other corporate projects, strategic analysis);
- (c) any costs in relation to human clinical trials in the UK other than the [\*\*\*]; and Required Commitments
- (d) any refundable or creditable Indirect Taxes, customs and excise duties, or similar taxes,

Cost of Product shall be calculated on the basis of the volume of units of Product that are the subject of Orders hereunder, and to the extent Cost of Product would be calculated as higher if Valneva Manufacture more units of Product than the volume that is the subject of Orders, then the lower Cost of Product shall be applied as if only the volume of Products the subject of Orders were Manufactured.

“**Crown**” means the government of the United Kingdom (including the Northern Ireland Assembly and Executive Committee, the Scottish Government and the Welsh Assembly Government), including, but not limited to, government ministers, government departments, government and particular bodies, and government agencies;

[\*\*\*] means [\*\*\*] payments made by or on behalf of the Crown to Valneva pursuant to the [\*\*\*];

[\*\*\*] means the [\*\*\*] and [\*\*\*] (it being acknowledged that these will relate to [\*\*\*] undertaken pursuant to the [\*\*\*] but that, for the avoidance of doubt, this may include expenditure on resources outside [\*\*\*] provided the trials themselves take place in [\*\*\*]);

“**Cure Period**” has the meaning given in clause 25.4.1;

“**Data Protection Laws**” means the Data Protection Act 2018 and all other applicable data protection and privacy legislation in force from time to time in the UK;

“**Delivery Location**” means the cold chain storage facilities within Great Britain notified by the Authority to Valneva from time to time;

“**Delivery Schedule**” has the meaning given in clause 9.1;

“**Development**” means all research, discovery, characterisation, preclinical, clinical and regulatory activity with respect to the Product (including the submission of filings with applicable Regulatory Authorities to support such preclinical and clinical activities and seek a Marketing Authorisation for the Product in the Territory with an indication in the Field), including undertaking all clinical studies necessary to support the grant of such a Marketing Authorisation and including post-approval trials and studies conducted after the Product receives such a Marketing Authorisation in order to (a) maintain that existing Marketing Authorisation; or (b) convert a conditional Marketing Authorisation granted for the Product in the Territory into an unconditional Marketing Authorisation where necessary. The term “**Developed**” and “**Develop**” shall have a corresponding meaning;

“**Development Activities**” means the Development activities to be undertaken by or on behalf of Valneva in respect of the Product as set out in the Development Plan;

“**Development Plan**” means the plan and timeline setting out in reasonable detail (a) the activities to be undertaken by or on behalf of Valneva in relation to the Development of Product for the Territory and including a high-level clinical and regulatory plan in respect of the Product for the Territory; and (b) the steps to be taken for the necessary clinical manufacturing required for the Product in the Territory; and (c) the regulatory plan and pathway proposed to secure the Marketing Authorisation for the Product in the Territory with an indication in the Field; and (d) the timeline to achieve Marketing Authorisation for the Product in the Territory with an indication in the Field; and (e) any Milestones in

relation to the foregoing; as such plan is initially set out in Schedule 4 and as may be periodically updated from time to time by the Parties in accordance with clause 4 in each case to meet the objectives of this Agreement to deliver a vaccine with a Marketing Authorisation in the Field for the UK population;

“**Devolved Administrations**” means the devolved administrations of Scotland, Wales and Northern Ireland (the Scottish Parliament, the Welsh Assembly and the Northern Ireland Assembly);

“**Documentation**” has the meaning given in clause 9.11;

“**Dose**” means a single individual dose of Product;

“**DOTAS**” means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customers of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992;

[\*\*\*] has the meaning given in clause [\*\*\*];

“**Effective Date**” means the date on which this Agreement is signed by both Parties;

“**Emergency Use Authorisation**” means any emergency use approval issued pursuant to Regulation 174 of the Human Medicines Regulations 2012 (or any replacement or superseding legislation);

“**Facilities**” means each and all of the facilities used by or on behalf of Valneva in respect of the Manufacturing of the Product, including those identified in Schedule 2;

“**Facility Plan**” means the plan setting out in reasonable detail the activities and steps to be taken in relation to (a) acquisition of OB2; (b) securing all planning consents, permits and licences which may be required to undertake the construction, update, upgrade and validation of each of OB1 and OB2; (c) the construction, update, upgrade, fitout and validation of the Facilities including all equipment, fittings and facilities at OB1 and OB2 such that they are suitable for the Manufacture of the Product in accordance with the Applicable Standards; (d) ensuring sufficient capacity at OB1 and OB2 for the Manufacture of the Product in accordance with the Orders placed hereunder (in accordance with [\*\*\*]); (e) ensuring that each of OB1 and OB2 are fully validated, certified and approved by the Licensing Authority for the Manufacture of the Product; (f) the timeline to secure readiness of OB1 and OB2 to Manufacture Product in sufficient quantities to meet the Delivery Schedule; and (g) any Milestones in relation to the foregoing; as such plan is initially set out in Schedule 5 and as may be periodically updated from time to time by the Parties in accordance with clause 3 in each case to meet the objectives of this Agreement to deliver a vaccine with a Marketing Authorisation in the Field for the UK population;

“**Field**” means the vaccination against SARS-CoV-2;

“**Final Payment Date**” means the date specified in 13.3.5;

“**Follow On Order**” has the meaning given in clause 8.2;

“**Force Majeure**” means any unforeseen events beyond a Party’s reasonable control, subject to that Party having taken all reasonable steps (both anticipatory and reactionary) to avoid or mitigate such risks, such as labour disturbances or labour disputes of any kind, accidents, civil disorders or commotions, war, acts of terrorism, acts of God, energy or other conservation measures, explosions, failure of utilities, mechanical breakdowns, material shortages, default of suppliers or sub-contractors, theft, or other occurrences. For the avoidance of doubt, (i) the withdrawal of the United Kingdom from the European Union; and (ii) the pandemic declared in respect of SARs-CoV-2 (but not, for the avoidance of doubt, any action which is not reasonably foreseeable and is required to be taken pursuant to any requirement or recommendation of any Governmental Authority in connection with such pandemic); are each foreseeable risks and shall not be deemed an event of Force Majeure;

“**Fraud**” any offence under Applicable Laws creating offences in respect of fraudulent acts, including any fraudulent acts in relation to this Agreement, or defrauding or attempting to defraud or conspiring to defraud the Crown;

“**Funds**” means monies [\*\*\*] to Valneva by the Authority by way of the Government [\*\*\*] Payments;

“**General Anti-Abuse Rule**” means (a) the legislation in Part 5 of the Finance Act 2013; and (b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;

“**Good Industry Practice**” means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled, experienced, professional and diligent supplier engaged in the development, manufacture and/or supply of goods similar to the Product under the same or similar circumstances as those applicable to this Agreement, including in accordance with any codes of practice published by relevant trade associations and/or industry bodies;

“**Government [\*\*\*] Payments**” means those amounts paid or to be paid by or on behalf of the Crown to Valneva [\*\*\*] in accordance with the Commitment Letter and clause 7 of this Agreement.

“**Governmental Authority**” means any government, supra-national, regional, regulatory or administrative body, authority, board, commission or agency, including any corresponding foreign agency or any instrumentality or officer acting in an official capacity of any of the foregoing, including any court, tribunal or judicial or arbitral body, or any committee exercising any executive, legislative, regulatory or administrative functions of government, whether local or national, including the Regulatory Authorities;

“**Guidance**” means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Product or medicinal products, to the extent that the same are published and publicly available by any of the Authority, NHS Improvement, NHS England, the MHRA, the European Medicines Agency or the

European Commission (in each case to the extent applicable to the UK), the Care Quality Commission and/or any other regulator or competent body, or the existence or contents of them where not published have been notified to Valneva by or on behalf of the Authority;

“**Halifax Abuse Principle**” means the principle explained in the CJEU Case C-255/02 Halifax and others;

“**Heads of Terms**” means the Heads of Terms entered into between Valneva and the Authority dated [\*\*\*];

“**Health Service Body**” means, in so far as they are involved in the administration, distribution or handling of the Product:

- (a) the Department of Health and all divisions and agencies thereof and any independent NHS board or similar body that may be established including regional agencies of such board;
- (b) a GP (being a medical practitioner providing general medical services or personal medical services under the National Health Service Act 2006 (c.41) (whether operating in partnership with others or not));
- (c) health service bodies referred to in section 9 of the National Health Service Act 2006 (c.41);
- (d) the Secretary of State for Health;
- (e) any care trust as defined in section 77 of the National Health Service Act 2006 (c.41);
- (f) any NHS foundation trust listed in the register of NHS foundation trusts maintained pursuant to section 39 of the National Health Service act 2006 (c.41);
- (g) any body replacing or providing similar or equivalent services to any of the above in any area of the United Kingdom including any bodies established pursuant to the Health and Social Care Act 2012 including but not limited to NHS England; and
- (h) any statutory successor to any of the above;

“**Indemnifying Party**” has the meaning given in clause 21.6;

“**Indemnitee**” has the meaning given in clause 21.6;

“**Indirect Tax**” means value added, sales, consumption, goods and services taxes or other similar taxes required by Applicable Law to be disclosed as a separate item on the relevant invoice including, for the avoidance of doubt, any tax imposed in compliance with the Council Directive of 28 November 2006 on the common system of value added tax (Directive 2006/112);

“**Initial Order**” has the meaning given in clause 8.1;

“**Initial Term**” has the meaning given in clause 25.1;

“**Intellectual Property Rights**” means all patent rights, supplemental protection certificates and patent term extensions, trademarks, copyrights, design rights, database rights, domain names, rights in inventions, confidential information, know-how, trade names, business names, get-up, logos and trade dress, and all other rights in the nature of intellectual property rights (whether registered or unregistered) and all applications and rights to apply for the above, anywhere in the world in each case for their full term and any extension thereto;

“**Irrevocably Committed**” means costs which are committed or spent by Valneva which:

- (a) with respect to items which are Required Commitments or [\*\*\*], are irrevocably committed or spent; and
- (b) with respect to items other than Required Commitments or [\*\*\*]:
  - (i) costs which have, at the relevant date, been paid with respect to those items and would not have been undertaken if Valneva had not undertaken the obligations under this Agreement or the [\*\*\*], and Valneva, using Commercially Reasonable Efforts, is unable to reduce or eliminate such actual expenditure; and
  - (ii) costs in respect of which, at the relevant date, Valneva has undertaken any commitment with respect to those costs which it would not have undertaken if Valneva had not undertaken the obligations under this Agreement or the [\*\*\*] and Valneva, using Commercially Reasonable Efforts, is unable to reduce or eliminate such commitment,

in either case it being acknowledged, for the avoidance of doubt, that if Valneva enters into an agreement to purchase, or to undertake or to complete, something and is required to pay an amount to a counterparty if it fails to do so and that amount cannot be refunded, Valneva shall be considered to be irrevocably committed to purchase, undertake or complete that thing;

“**IT Media**” has the meaning given in clause 20.16;

“**JSC**” means the joint steering committee established by the Parties in accordance with clause 2;

“**KPI**” or “**Key Performance Indicators**” means those key performance indicators against which the Authority will monitor certain performance activities as set out in Schedule 3;

“**Labelling**” means all labels, package inserts (including patient information leaflets), carton imprints and all other markings on packaging for the Product that are defined as labels or labelling under the Specifications or otherwise required under Applicable Laws to market or commercialise the Product for use in the Territory;

“**Licensing Authority**” means (i) the MHRA; or (ii) if it has authority under the Applicable Laws of the Territory to grant a Marketing Authorisation that has full legal



force in the Territory to authorise commercial use of the Product in the Territory after its Delivery hereunder, the European Commission following assessment of the relevant Marketing Authorisation application by the European Medicines Agency (“EMA”) or any successor agency thereto with the same authority in the UK;

“**Losses**” means any and all liabilities, claims, demands, causes of action, damages, losses, costs and expenses, including interest, penalties and reasonable legal and professional fees and disbursements;

“**Loss of Supply**” has the meaning given in clause 9.7;

“**Manufacture**”, “**Manufactured**” or “**Manufacturing**” means all activities involved in or relating to the manufacturing, quality control testing (including in-process, release and stability testing), processing, Labelling, releasing, packaging, storage and transport of the Product immediately prior to supply to the Authority hereunder;

“**Manufacturing Plan**” means the plan setting out in reasonable detail the activities and steps to be taken (excluding those in the Facility Plan) for the Manufacture and Delivery of Product in accordance with the Delivery Schedule together with the timeline applicable to such activities and any Milestones in relation to the foregoing; as such plan is initially set out in Schedule 6 and as may be periodically updated from time to time by the Parties in accordance with clause 2 in each case to meet the objectives of this Agreement to manufacture a vaccine with a Marketing Authorisation in the Field for the UK population;

“**Margin**” means such amount that is equal to the [\*\*\*] of the [\*\*\*] Follow On Order [\*\*\*], in each case such [\*\*\*] excluding the [\*\*\*] and the Required Commitments;

“**Marketing Authorisation**” means the Regulatory Approval required under Applicable Laws to place a medicinal product on the market in the Territory for human use outside of clinical trials, including any conditional use approval or any approval issued pursuant to Directive 2001/83/EC or Part 5 of the Human Medicines Regulations 2012 (or any replacement or superseding legislation), but excluding any pricing or reimbursement approvals;

“**MHRA**” means the Medicines and Healthcare products Regulatory Agency or any successor agency thereto;

“**Milestone**” means as applicable to the context and obligations (a) the Milestones listed in the Development Plan; (b) the Milestones listed in the Facility Plan; and (c) the Milestones listed in the Manufacturing Plan;

“**Minimum Shelf Life**” means the minimum period for which the Product is useable calculated from completion of fill finish of the Product, [\*\*\*] provided that the Product is stored under the specified storage conditions according to the SmPC, and which period may be extended from time to time in accordance with clause 5.20;

“**Minimum Viable Marketing Authorisation**” means a Marketing Authorisation fulfilling the requirements of clause 4.7;

“**Net Funding**” means, at any time, any amount by which the aggregate of any Funds, [\*\*\*] and payments of instalments under clause 13 [\*\*\*] to Valneva exceeds the [\*\*\*] of:

- (a) the amount of benefit received by the Authority [\*\*\*] through Delivery of Conforming Product; and
- (b) any other amounts recovered by the Authority in respect of Funds previously [\*\*\*] to Valneva;

“**Non-Compliance**” or “**Non-Compliant**” means, in respect of a Product, that at the time of Delivery is not compliant with the Specification, the Marketing Authorisation for the Product with an indication in the Field, batch records, Applicable Standards or Minimum Shelf Life or Applicable Laws;

“**OB1**” means the existing manufacturing facility site at [\*\*\*], Livingston [\*\*\*], United Kingdom;

“**OB2**” means the additional manufacturing facility site adjacent to or nearby to OB1 located at [\*\*\*], Livingston [\*\*\*], United Kingdom;

“**Occasion of Tax Non-Compliance**” means:

- (a) any tax return of Valneva submitted to a Relevant Tax Authority on or after 1 October 2012 is found, on or after 1 April 2013, to be incorrect as a result of:
  - (i) a Relevant Tax Authority successfully challenging Valneva under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; or
  - (ii) the failure of an avoidance scheme which Valneva was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; or
- (b) any tax return of Valneva submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion;

“**Off Label Use**” means any use of any Product supplied pursuant to this Agreement that is (i) use outside of the Field; and (ii) use which does not comply with the terms of use for that Product as set out in the Summary of Product Characteristics document approved as part of the Marketing Authorisation for the Product;

“**Orders**” means each of the Initial Order and (if applicable) the Follow On Order and any Additional Order;

“**Paid Amounts**” means at any time any amount then paid by the Authority to Valneva pursuant to this Agreement [\*\*\*];

“**Person**” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture, Governmental Authority, or similar entity, institution, body or organisation, including a Regulatory Authority;

“**Personal Data**” shall have the same meaning as defined in the Data Protection Laws;

“**Personnel**” means the employees, officers, agents and contractors of a Party or (where, the context requires, those of a Party’s Affiliates);

[\*\*\*] means [\*\*\*] as defined in the [\*\*\*] conducted on [\*\*\*] with the principal purpose of [\*\*\*] towards seeking a Minimum Viable Marketing Authorisation in the Territory;

[\*\*\*] means costs incurred pursuant to the [\*\*\*] in connection with the [\*\*\*];

[\*\*\*] means [\*\*\*] conducted on [\*\*\*] subjects following the [\*\*\*] but prior to conducting [\*\*\*], with the principal purpose of [\*\*\*] towards seeking a Minimum Viable Marketing Authorisation in the Territory;

[\*\*\*] means costs (other than the [\*\*\*]) incurred pursuant to the [\*\*\*] to secure a Minimum Viable Marketing Authorisation;

[\*\*\*] means [\*\*\*] conducted on [\*\*\*] following [\*\*\*] to [\*\*\*] towards seeking a Minimum Viable Marketing Authorisation in the Territory;

“**Plans**” means the Facility Plan, Manufacturing Plan and Development Plan;

“**Price**” means, the total price payable by the Authority in respect of the Product (either in the context of a Dose, Regimen or Order, as applicable) calculated pursuant to the provisions of clause 13, as such amounts may be varied in accordance with the reconciliation provisions of clause 13;

“**Product**” means the Candidate as developed in accordance with the Development Plan, presented in final formulated, labelled and finished form indicated for the prophylaxis and vaccination against SARS-CoV-2 in humans and (unless the context requires otherwise) in accordance with the Marketing Authorisation issued in the Territory;

“**Project Manager**” has the meaning given in clause 2.1;

“**Regimen**” means the dosing regimen approved for the Product for the primary vaccination of a single person, which is anticipated as of the Effective Date to comprise two Doses per patient;

“**Regulatory Approval**” means all technical, medical and scientific licences, registrations, authorisations and approvals (including approvals of CTAs, MAAs, supplements and amendments, pre- and post- approvals and labelling approvals) issued by any Regulatory Authority, which are necessary or useful for the use, Development, Manufacture, and commercialisation of a pharmaceutical or biopharmaceutical product in a country or regulatory jurisdiction;

**“Regulatory Authority”** means any Governmental Authority that is concerned with the safety, efficacy, reliability, Manufacture, investigation, sale or marketing of the Product, including the MHRA and its successors in the Territory;

**“Relevant Tax Authority”** means HM Revenue & Customs;

**“Representation”** has the meaning given in clause 35.9;

**“Representatives”** has the meaning given in clause 20.2;

**“Required Commitments”** means subject to the aggregate amount set forth in Schedule 9 under the column “Total”, those costs associated with the definitive list of categories in Schedule 9 [\*\*\*];

**“Sanctions Guidelines”** means the UK Government’s sanctions guidelines as amended from time to time, the current versions as at the date of this Agreement being set out in Schedule 13;

**“Solna Facility”** means Valneva’s existing manufacturing facility site in Solna, Sweden;

**“Specification”** means the written specifications for the manufacture, processing, packaging, labelling, testing and testing procedures, shipping, storage and supply of the Product, including characteristics, quality and processing of the Candidate and Product a current outline of which is set out in Schedule 1, and as will be set forth with respect to such Product in the applicable Marketing Authorisation, for the Territory, as such specifications may be amended or replaced from time to time as permitted under the Development Plan or otherwise under this Agreement;

**“Sponsor”** has the meaning ascribed to it in European Commission Directive 2001/20/EC;

**“Subcontractor”** has the meaning given in clause 35.6.1;

**“Supplier Code of Conduct”** means the Authority’s supplier code of conduct, as amended by the Authority from time to time, the current version as of the date of this Agreement being set out in Schedule D of the [\*\*\*];

**“Term”** has the meaning given in clause 25.1;

**“Terminating Party”** has the meaning given in clause 25.4;

**“Territory”** means the United Kingdom of Great Britain and Northern Ireland;

**“Third Party”** means any Person other than Valneva, the Authority and their respective Affiliates and permitted successors and assigns;

**“UK Vaccine Taskforce”** means the vaccine taskforce set up by the Government’s Chief Scientific Adviser, Deputy Chief Medical Officer, Business Secretary and Health Secretary to lead, expedite and co-ordinate efforts in the UK to research and manufacture a vaccine for the treatment of SARS-CoV-2;

**“Valneva Representatives”** has the meaning given in clause 17.1;

“VAT” means: (i) any Indirect Tax chargeable under or pursuant to Council Directive 2006/112/EC of the European Union; or (ii) any value added, turnover, sales, use or distribution Indirect Tax, or Indirect Tax of a like nature in any jurisdiction outside the European Union;

“Wilful Misconduct” shall mean an act or omission taken (a) intentionally to achieve a wrongful purpose; (b) recklessly, or knowingly without legal or factual justification; or (c) in disregard of a known or obvious risk that makes it reasonably probable that harm associated with the risk will arise.

1.2 In this Agreement the following rules of interpretation shall apply:

- 1.2.1 the words “**hereof**”, “**herein**”, “**hereto**” and “**hereunder**” and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement;
- 1.2.2 when a reference is made in this Agreement to a clause or schedule, such reference is to a clause of or a schedule to this Agreement respectively, and all schedules to this Agreement form a part hereof for all purposes;
- 1.2.3 the table of contents and headings of this Agreement are for convenience only and shall not affect the construction of this Agreement;
- 1.2.4 any reference to an English statutory provision or English legal term for any action, remedy, method of judicial proceeding, document, legal status, court, official or any other legal concept or thing or Applicable Law shall in respect of any jurisdiction other than England be deemed to include what most nearly approximates in that jurisdiction to the English statutory provision or English legal term;
- 1.2.5 any reference to European Union law or a European Union legal term for any action, remedy, method of judicial proceeding, document, legal status, court, official or any other legal concept or thing or Applicable Law shall in respect of the Territory be deemed to include what most nearly approximates in the Territory to the European Union statutory provision or European Union legal term;
- 1.2.6 any undertaking by, or obligation on, a Party to (i) do any act or thing includes an undertaking to procure the doing of that act or thing by a Party’s Affiliate; and, (ii) not do any act or thing includes an undertaking not to encourage, solicit, cause, or assist the doing of that act or thing by any Affiliate or other person;
- 1.2.7 the words and expressions “**holding company**”, “**parent undertaking**”, “**subsidiary**” and “**subsidiary undertaking**” have the meanings given to them in the Companies Act 2006;
- 1.2.8 any reference to a **Party** or the **Parties** is to a party or the parties (as the case may be) to this Agreement and shall include legal successors and/or any permitted assignees of a party;

- 1.2.9 any use of the masculine, feminine or neuter gender respectively includes the other genders and any reference to the singular includes the plural (and vice versa);
- 1.2.10 the words “**other**”, “**include**”, “**including**”, “**such as**” and “**in particular**” (and similar expressions) do not connote limitation in any way and will be deemed to be followed by the phrase “without limitation”;
- 1.2.11 any reference to a “**month**” means a calendar month, any reference to a “**day**” means a calendar day;
- 1.2.12 any reference to GBP, Pounds Sterling or £ is to the lawful currency from time to time of the United Kingdom of Great Britain and Northern Ireland and to the European Union;
- 1.2.13 any reference to a **statute** or **statutory provision** includes any successor legislation thereto, regulations promulgated thereunder, any consolidation or re- enactment, modification or replacement thereof, any statute or statutory provision of which it is a consolidation, re-enactment, modification or replacement and any subordinate legislation in force under any of the same from time to time except in each case to the extent that any consolidation, re- enactment, modification or replacement enacted after the date of this Agreement would extend or increase the obligations, in any manner (and whether financial obligations or otherwise), of either Party hereunder;
- 1.2.14 any reference to “**open book**” shall, in relation to the determination or estimate in question, require the provision of reasonable information to evidence and substantiate such determination or estimate and, to the extent reasonably necessary, the individual items comprised in such determination or estimate, including, where relevant and to the extent reasonably necessary, access to accounting books and records, copies of working and supporting papers and bank account statements and access for discussions with the relevant companies’ auditors and advisers;
- 1.2.15 provisions that require that a Party, the Parties or any committee hereunder to “**agree**”, “**consent**” or “**approve**” or the like will require that such agreement, consent or approval be specific and in writing (including via email), whether by written agreement, letter, approved minutes or otherwise;
- 1.2.16 the term “**or**” and “**and/or**” will be interpreted in the inclusive sense commonly associated with the term “**and/or**”;
- 1.2.17 the words “**notify**” and “**notification**” in this Agreement shall, when referring to notifications as between the Parties to this Agreement (or their representatives), mean notify or notification in writing in accordance with clause 35.1 of this Agreement;
- 1.2.18 any reference to “**writing**” or “**written**” shall include any modes of reproducing words in a legible and non-transitory form (including email, but excluding SMS or temporary messages); and

- 1.2.19 where this Agreement refers to any commitment, cost, expenditure or other transaction (including, without limitation, Required Commitments) being incurred or undertaken by Valneva pursuant to and in accordance with the performance of this Agreement and for which the Authority is to be liable hereunder, that reference shall include, and the provisions of this Agreement shall operate in respect of, such commitments, cost, expenditure or transaction to the extent properly incurred and undertaken by any Affiliate of Valneva in discharging the obligations of Valneva pursuant to and in accordance with the performance of this Agreement.
- 1.3 In case of a conflict between the provisions of any schedule and the provisions of the main body of this Agreement, the provisions of the main body of this Agreement shall prevail.
- In this Agreement the Authority is acting as part of the Crown.

## 2. GOVERNANCE

### Project Managers

- 2.1 From the Effective Date each Party shall appoint, and provide details to the other Party, of its project manager (“**Project Manager**”) who shall be responsible for and represent the applicable Party in liaison between the Parties concerning performance and progress under this Agreement against the Plans together with monitoring delivery against the Milestones and each of the KPIs. The Project Managers shall facilitate the relationship between the Parties under this Agreement, by providing regular reports on that progress against the Plans, discussing performance of each Party under this Agreement and collate matters and issues that may be necessary for referral to the JSC. Each Party shall procure that its respective Project Manager shall:
- 2.1.1 make themselves reasonably available to the other Project Manager for meetings in accordance with the provisions of this clause 2;
- 2.1.2 co-operate candidly and transparently with the other Project Manager to ensure that any actual or potential issues, difficulties or problems encountered in connection with the Product, its Development, Manufacture and supply, in each case under this Agreement and to the extent the same is reasonably likely to impact any Milestone, performance of any obligation hereunder or the Authority, are raised and discussed between Project Managers at the earliest opportunity;
- 2.1.3 be a person of reasonable management seniority who is part of the relevant Party’s team working on and has good first-hand knowledge of the arrangements and matters relating to this Agreement; and
- 2.1.4 ensure that they appraise themselves and keep themselves appraised of all material matters and issues concerning this Agreement and its performance.
- 2.2 The Project Managers shall monitor and discuss (a) progress in relation to each of the Plans, Milestones and KPIs; (b) any issues or delays in performance against the Plans, Milestones or KPIs; (c) and, where appropriate, agree any changes to the Delivery Schedule; (d) review and make recommendations to the JSC for any material updates of

the Development Plan, Facility Plan and/or Manufacturing Plan; and (e) review and propose mitigations to the JSC on risks and issues that may have a material impact on fulfilment and/or achievement of the Milestones, KPIs and Plans. Each Party shall use reasonable efforts to minimise a change of its Project Manager, but any change of a Project Manager shall be notified as soon as reasonably possible in writing and each Party shall use reasonable endeavours to ensure notice of any change on no less than one (1) month's prior written notice.

- 2.3 Valneva shall ensure that Valneva's Project Manager promptly notifies and keeps the Authority's Project Manager promptly informed of all material activities under and progress to satisfactorily complete and fulfil the Plans, Milestones and KPIs.

#### Project Manager Meetings

- 2.4 The Project Managers will meet at such times as they reasonably elect to do so provided that they shall meet in accordance with the frequency and schedule set forth in Schedule 3; unless in any of the foregoing cases they both agree to any alternative meeting schedule. The Project Managers shall meet virtually via a secured digital platform (or physically subject to observing then current social distancing guidelines and travelling restrictions). Additionally, either Project Manager may call a special meeting at any time; provided that the requesting Party provides at least [\*\*\*] prior notice to the other Project Manager and such notice includes a proposed agenda for such meeting. If a Project Manager cannot attend a meeting, they may nominate a person of appropriate seniority and experience within their organisation to attend that meeting in their place. Each Party will be solely responsible for its own Project Manager's expenses relating to attending and participating in the meetings. As appropriate, other representatives and consultants of the Parties may attend such meetings.

#### Joint Steering Committee

- 2.5 In addition to the appointment of Project Managers, the Parties shall establish a joint steering committee that shall be responsible for monitoring the progress of the project contemplated by this Agreement and for making those decisions delegated to it pursuant to this clause 2.

#### JSC Responsibilities

- 2.6 The JSC shall have non-executive oversight of and responsibility for:
- 2.6.1 encouraging and facilitating ongoing communication and cooperation between the Parties with respect to each Party's obligations under this Agreement;
  - 2.6.2 monitoring and discussing any material issues concerning the Development of the Product including the establishment and conduct of the clinical trials (including where such trials would best be located), funding and cash forecasts to complete the Development and the filing, prosecution and issuance of any Regulatory Approval for the Product;
  - 2.6.3 discussing and resolving any material issues concerning: (i) the acquisition, construction, fitout, establishment and validation of each of OB1 and OB2, (ii) the progress towards the Milestones set out in the Facility Plan (including funding and cash forecasts to fulfil the same), and (iii) establishing the Manufacturing supply chain;



- 2.6.4 discussing and resolving any material issues or delays in the Manufacturing progress or Delivery of Product, and monitoring the resolution of those issues or delays;
  - 2.6.5 reviewing and agreeing any Milestones or updates of a material nature to the Development Plan, Facility Plan and/or Manufacturing Plan proposed by Valneva and provided to the JSC in accordance with this Agreement;
  - 2.6.6 monitoring and resolving any issues concerning Valneva's performance under this Agreement;
  - 2.6.7 reviewing and, where appropriate, agreeing any changes to the Delivery Schedule;
  - 2.6.8 raising and determining mechanisms to resolve any issues, difficulties, problems or obstacles in the Development or Manufacture of the Product to the extent that such issues, difficulties, problems or obstacles will have a material impact on the supply of the Product to the Authority in accordance with this Agreement;
  - 2.6.9 resolving disputes referred to it by a Party or Project Manager;
  - 2.6.10 monitoring capacity and scale up activities for clinical and commercial supplies including reporting on funding and cash forecasts to fulfil the same;
  - 2.6.11 matters relating to the calculation of Cost of Product;
  - 2.6.12 monitoring the progress of the Manufacturing and Development of the Product by reference to the Milestones (where appropriate) in each of the Development Plan, Facilities Plan and Manufacturing Plan; and
  - 2.6.13 discussing and agreeing arrangements for [\*\*\*] arrangements and concluding agreements on [\*\*\*] from Valneva and its Affiliates, each in accordance with clause 16,
- in each case to the extent that such matters relate to, or may impact on, the Development, Manufacture and/or supply of Product to the Authority in accordance with this Agreement.

#### Membership of the JSC

- 2.7 The JSC shall comprise an equal number of representatives from each of the Parties or their Affiliates (collectively, "the **Members**"). The number of Members representing each Party at the JSC shall be [\*\*\*] or such other number as the Parties may mutually agree. Each Party may replace any or all of its Members on the JSC at any time upon written notice to the other Party provided that any replacement Members are employees or officers of that Party or that Party's Affiliates, have the appropriate skill and experience to perform the duties of a Member and sufficient seniority and authorisation on behalf of the applicable Party to make decisions arising within the scope of the JSC.

- 2.8 Any Member of the JSC may designate a suitable substitute who is an employee or of that Member at any meeting of the JSC. Each Party may, in its reasonable discretion, invite non-Member representatives of such Party to attend meetings of the JSC as a non-voting contributor, provided that such persons are bound by confidentiality obligations no less stringent than those of clause 20.
- 2.9 The Authority shall appoint a chairperson of the JSC to oversee the operation of the JSC.

#### Meetings of the JSC

- 2.10 The JSC shall meet [\*\*\*], or more or less frequently as the Parties or the Members may mutually deem appropriate provided that where a dispute has been referred to the JSC for resolution the JSC shall meet within [\*\*\*] of such referral in order to resolve such dispute (or sooner if required).
- 2.11 The first JSC meeting shall be no later than [\*\*\*] after the Effective Date.
- 2.12 The JSC may meet virtually via a secured digital platform, or where necessary it may meet physically subject to observing then current social distancing guidelines and travelling restrictions. Either Party may also call a special meeting of the JSC (via a secure digital platform) upon at least [\*\*\*] prior written notice to the other Party, or such shorter period as may be agreed on a meeting-by-meeting basis, if such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the JSC (as applicable) no later than [\*\*\*] prior to the special meeting with materials reasonably adequate to enable an informed understanding to be made by its Members. Each Party shall be responsible for its own expenses relating to such meetings. The chairperson of the JSC shall be responsible for preparing reasonably detailed written minutes of all JSC meetings.

#### Decision Making

- 2.13 Except as otherwise expressly provided in this Agreement, where a matter requires the consent, approval or agreement of the JSC in accordance with this Agreement, such decision shall be made by [\*\*\*] of a quorum of the Members, with each Party having [\*\*\*] vote. The presence of at least [\*\*\*] representing each Party (i.e. a total of at least [\*\*\*]) shall constitute a quorum of the JSC. The Members shall endeavour in good faith to reach agreement on any and all matters to be determined or resolved by the JSC.
- 2.14 Each Party shall ensure that where, in accordance with this Agreement, a matter is referred to the JSC for consent, approval or agreement, that Party's Members of the JSC appointed by it shall act reasonably and should not unreasonably withhold or delay such consent, approval or agreement.
- 2.15 If at any time, the JSC is unable to reach a unanimous decision within [\*\*\*] (or sooner if required) after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such matter referred for resolution by an appropriate senior executive officer of each Party. Within [\*\*\*] (or sooner if required) of such notice, the relevant senior executives and member shall meet and attempt to resolve the dispute by good faith negotiations.

Notifications: Milestone Requirements

- 2.16 Subject to clause 2.17, Valneva shall ensure (through its Project Manager or the JSC) that:
- 2.16.1 it will alert and discuss with the Authority within [\*\*\*] if any issues which it cannot promptly resolve are encountered in relation to sourcing, securing, purchasing or leasing any Required Commitment;
  - 2.16.2 it will alert and discuss with the Authority within [\*\*\*] if there are material price changes to any of the Required Commitment;
  - 2.16.3 it will alert and discuss with the Authority within [\*\*\*] if negotiations with [\*\*\*] produce any issues of concern that may negatively impact Milestones, deadlines, the Facility Plan, the Development Plan, the Manufacturing Plan and / or the overall objectives of this Agreement;
  - 2.16.4 it will alert and discuss with the Authority within [\*\*\*] if there are any adverse developments relevant to securing a timely agreement with [\*\*\*] for adjuvant such as notification or knowledge of activation of the [\*\*\*] (or any other policy) which may prevent or limit supply of adjuvant by [\*\*\*] to the extent that such limited supply will impact upon the supply of the Product to the Authority in accordance with this Agreement.
  - 2.16.5 it will alert and discuss with the Authority within [\*\*\*] if any issues arise in relation to securing any necessary planning consents, approvals, qualifications, or similar authorisations from any relevant Third Party which are required to permit Valneva, or Valneva's sub-contractors, to adapt any existing facilities and/or construct any new facilities as anticipated in the Facility Plan.
  - 2.16.6 it will alert and discuss with the Authority within [\*\*\*] if any issues arise in relation to securing any necessary planning consents, approvals, qualifications or similar authorisations from any relevant Third Party which are required to permit Valneva, or Valneva's sub-contractors, to handle, install, operate, (or similar) any equipment or material, as part of the adaption of any existing facilities and/or the construction of any new facilities as anticipated in the Facility Plan, the Development Plan or the Manufacturing Plan;
  - 2.16.7 it will alert and discuss with the Authority within [\*\*\*] if any issues arise that may negatively impact project timelines, Milestones or result in a price change relating to the upgrade of the existing OB1 facility and/or construction of the OB2 facility or that otherwise adversely impacts achievement of any part of the Development Plan, Facilities Plan, the Manufacturing Plan or the Delivery Schedule.
- 2.17 Valneva may fulfil its obligations under clause 2.16 by providing a [\*\*\*] report (or at such other frequency jointly agreed between the Project Managers of both Parties) to the Authority provided that the foregoing shall not excuse Valneva from meeting the deadlines for notification on the matters set out in clause 2.16.

3. **MANUFACTURING FACILITY ESTABLISHMENT**

Execution of Facility Plan

- 3.1 Valneva confirms that the Facility Plan represents its plan for the matters dealt with therein and that it will perform and execute that plan in all material respects and use Commercially Reasonable Efforts to do so in accordance with the Milestones and timelines set out therein, including procuring that its Affiliates provide, the human and other resources, materials, facilities and equipment required for the Facility Plan.
- 3.2 The Facility Plan at Schedule 5 and any update thereto shall:
- 3.2.1 set out details and estimated timelines for the acquisition, construction, fitout, commissioning and licensing of the OB1 and OB2 facilities together with the acquisition, installation and commissioning of the equipment therein, in each case to deliver facilities suitable for the Manufacture of the Product to enable its supply to the Authority in accordance with the provisions of this Agreement to enable its supply to the Authority hereunder, provided that the Facility Plan shall be adjusted and updated by Valneva (subject to requiring the JSC's consent insofar as any change or update affects a Milestone or is a material change or update) as such activities progress whereupon the plans for such activities will become more focused, specific and detailed, with details of any updates to the Facility Plan being provided to the JSC on a [\*\*\*] basis in accordance with clause 3.4;
- 3.2.2 be consistent with the provisions and objectives of this Agreement to achieve a Manufacturing facility within the Territory that is suitable for and has sufficient capacity for the Manufacture and Delivery of the Product in the Territory in accordance with the Delivery Schedule; and
- 3.2.3 not impose obligations on the Authority and/or Authority's Affiliates with respect to such activities.
- 3.3 In undertaking, or having undertaken on its behalf, all acts necessary in order to perform and execute the Facility Plan, Valneva shall:
- 3.3.1 act in accordance with and shall perform and have performed all such activities in the Facility Plan and in accordance with Good Industry Practice;
- 3.3.2 have regard to and implement any reasonable recommendations made by the JSC in executing and delivering the Facility Plan;
- 3.3.3 ensure that OB1 and OB2 are satisfactorily constructed, fitted out, equipped, commissioned, licensed and validated:
- (a) to meet the Applicable Standards, including securing all necessary Regulatory Approvals and licences required for the manufacture of human vaccine products;
- (b) for the Manufacture of the Products and in sufficient scale and volume to meet the Orders and the Delivery Schedule; and
- 3.3.4 as soon as reasonably practicable, remedy and rectify any problems, deficiencies or defects concerning any construction, fit out, equipment or commissioning of OB1 and OB2 to the extent that the same may have an adverse impact on the supply of the Product to the Authority in accordance with this Agreement;

- 3.3.5 comply with all material obligations relating to any real estate obligations in connection with OB1 and OB2 including all covenants, charges, and terms of leases; and
- 3.3.6 comply with all Applicable Laws in such activities including all laws relating to planning, construction, environmental and health and safety matters.

#### Updates to the Facility Plan

- 3.4 Valneva shall maintain the Facility Plan and keep this up to date, providing a copy of the then most recent Facility Plan to the JSC on a [\*\*\*] basis unless otherwise agreed by the Parties. Any material change to the Facility Plan or change that affects a Milestone must be agreed by the JSC before becoming effective. The Parties agree that the sections of the Facility Plan detailing the activities to be undertaken in the then coming [\*\*\*] of the Facility Plan will necessarily include more detail and specificity than later portions of the Facility Plan which may be subject to further revision as the plan is updated. Valneva may make recommendations for amendments to be made to the Facility Plan (subject to requiring the JSC's consent insofar as any change or update affects a Milestone or is a material change or update), and Valneva must have due regard to such amendments when complying with its obligations in this clause 3.4 to keep the Facility Plan up to date.
- 3.5 Notwithstanding the process pursuant to clause 3.4, if the Parties agree that the Facility Plan is incomplete or deficient for the purposes of ensuring that OB1 and OB2 are suitable for the supply of Product to the Authority pursuant to this Agreement, then the Parties shall in good faith negotiate and agree via the JSC any revision to the Facility Plan that will remedy and correct such incompleteness or deficiency.

#### Responsibility for fulfilling the Facility Plan

- 3.6 Without prejudice to the Authority's obligations to pay the specified amounts under this Agreement: (i) Valneva shall be responsible at its own cost and expense for the implementation and execution of the Facility Plan and establishing the Facilities to be suitable for Manufacture of Conforming Product in accordance with Applicable Laws, the Orders and Delivery Schedule; and (ii) for the avoidance of doubt, the Authority shall have no obligation to perform any acts or fund (other than any payments due under clause 7) any activities under the Facility Plan.

#### Facilities for Manufacture of the Product

- 3.7 Valneva represents to the Authority as at the date of this Agreement that Schedule 2 contains the complete list of all Facilities that are currently anticipated to be involved or required in any aspect of the Manufacturing of the Product.
- 3.8 Valneva shall not, and shall procure that its Subcontractors shall not, use any other facilities, beyond those listed in Schedule 2, for the Manufacture of the Product, *provided that*, should any change to or new facilities need to be added to Schedule 2, (i) the consent of the JSC shall be required (such consent not to be unreasonably withheld or delayed); and (ii) Valneva will provide reasonable information to the Authority regarding such change and the reasons therefor and shall discuss such changes in good faith at the JSC.

- 3.9 Valneva either owns or operates the Facilities, or has or will have a legally binding agreement in place, in each case in order to use, or have used, the Facilities for the purposes of Manufacturing Product pursuant to this Agreement and to ensure the supply and Delivery of Product in accordance with this Agreement.

#### Maintenance of Facilities

- 3.10 At all times during the Term (following the fit out of OB1 and OB2) and when the Facilities are required to Manufacture Product to be supplied pursuant to this Agreement), Valneva shall:
- 3.10.1 keep, or procure the keeping of the Facilities in a state and condition that meets GMP, Good Industry Practice and is suitable and necessary for the successful Manufacture of the Product to enable Valneva to comply with its obligations to supply Conforming Product to the Authority in accordance with this Agreement;
  - 3.10.2 hold all necessary Regulatory Approvals to operate the Facilities for the Manufacture of Product, and Manufacture Conforming Product for supply and Delivery, under and in accordance with this Agreement; and
  - 3.10.3 permit or procure permission for the Authority or the Authority's nominees during normal business hours having given reasonable advance notice access to the Facilities to enable the Authority (or its nominees) to inspect and review the Manufacturing activities, and the quality assurance processes in relation to the Product (such access to be subject to all such individuals being required to undertake reasonable obligations of confidentiality and comply with all reasonable rules for access to those Facilities).

#### Information Disclosures

- 3.11 Upon request by the Authority, Valneva shall respond to all reasonable enquiries and requests for information made by the Authority regarding the establishment of OB1 and OB2 for the Manufacture of the Product for supply to the Authority in accordance with this Agreement (including the status and progress of regulatory licensing and approval process for the facilities). Without prejudice to the foregoing, through the Project Managers and JSC, Valneva shall include in its [\*\*\*] report, provided in accordance with clause 2.17, details of its progress towards achieving the Milestones in the Facility Plan.

#### Validation Commitment

- 3.12 Valneva shall ensure that pursuant to its applications for the Marketing Authorisation in respect of the Product in the Territory it shall (i) ensure that the Facilities conform with all Applicable Standards; and (ii) use Commercially Reasonable Efforts to qualify and validate the Facilities for the Manufacture of Products.

#### 4. DEVELOPMENT, REGULATORY OBLIGATIONS AND INFORMATION REQUIREMENTS

##### Obligation to Develop the Product

- 4.1 Valneva shall use Commercially Reasonable Efforts to Develop the Candidate in order for it (or its Affiliate) to secure a Marketing Authorisation in the Territory for the Product with an indication in the Field, and in doing so shall follow and implement the Development Plan in all material respects and shall use Commercially Reasonable Efforts to do so in accordance with the Milestones and timelines set out therein, including procuring that its Affiliates provide, the human and other resources, materials, facilities and equipment required for the Development Plan.

##### Execution of the Development Plan

- 4.2 The Development Plan at Schedule 4 and any update thereto shall:

- 4.2.1 set out details and estimated timelines for the Development of the Candidate and Product, provided that the Development Plan shall be adjusted and updated by Valneva (subject to requiring the JSC's consent insofar as any change or update affects a Milestone or is a material change or update) as Development progresses and the plans for such Development will become more focused, specific and detailed, with details of any updates to the Development Plan being provided to the JSC on a [\*\*\*] basis in accordance with clause 4.4;
- 4.2.2 be consistent with the provisions and objectives of this Agreement to achieve a Marketing Authorisation for the Product in the Territory for an indication within the Field by [\*\*\*]; and
- 4.2.3 not impose obligations on the Authority and/or Authority's Affiliates unless the Authority has agreed in writing to assume responsibility for such obligations.

- 4.3 In undertaking, or having undertaken on its behalf, all acts necessary in order to perform and execute the Development of the Product, including performing and executing the Development Plan, Valneva (or its Affiliate) shall:

- 4.3.1 perform, and have performed, all such activities required to fulfil and meet the Development Plan in accordance with the Applicable Standards and Good Industry Practice;
- 4.3.2 have regard to and implement any directions or any recommendations made by the JSC in executing and delivering the Development Plan;
- 4.3.3 obtain and maintain all Regulatory Approvals and ethical and other approvals necessary to allow it or its Affiliates (or others on their behalf) to carry out the Development of the Product including the tasks in the Development Plan;
- 4.3.4 ensure that any clinical trials undertaken are performed in accordance with Good Industry Practice and in accordance with:
- (a) the Applicable Standards relevant to such trials, including securing all necessary Regulatory Approvals required for undertaking the trials, including those of any ethics committee;

- (b) any designated protocol approved by the Regulatory Authority in the Territory and the applicable ethics committee and principal investigators so retained; and
  - (c) the terms of the [\*\*\*];
- 4.3.5 as soon as reasonably practicable, remedy and rectify any problems, deficiencies or defects concerning the Development of the Product to the extent that the same may have any adverse impact on the supply of the Product in accordance with this Agreement; and
- 4.3.6 comply with all Applicable Laws and Applicable Standards in such activities including all Data Protection Laws.

#### Updates to the Development Plan

- 4.4 Valneva shall maintain the Development Plan and keep this up to date, providing a copy of the then most recent Development Plan to the JSC on a [\*\*\*] basis unless otherwise agreed by the Parties. Any material change to the Development Plan or change that affects a Milestone must be agreed by the JSC before becoming effective. The Parties agree that the sections of the Development Plan detailing the Development Activities to be undertaken in the then coming [\*\*\*] of the Development Plan will necessarily include more detail and specificity than later portions of the Development Plan which may be subject to further revision as the plan is updated. Valneva may make recommendations for amendments to be made to the Development Plan (subject to requiring the JSC's consent insofar as any change or update affects a Milestone or is a material change or update), and Valneva must have due regard to such amendments when complying with its obligations in this clause 4.4 to keep the Development Plan up to date.
- 4.5 Notwithstanding the process pursuant to clause 4.4, if the Parties agree that the Development Plan is incomplete or deficient for the purposes of Development of the Product for supply in accordance with this Agreement, then the Parties shall in good faith negotiate and agree via the JSC any revision to the Development Plan that will remedy and correct such incompleteness or deficiency.

#### Responsibility for fulfilling the Development Plan

- 4.6 Valneva shall be responsible at its own cost and expense for the Development of the Product, the implementation and execution of the Development Plan and for undertaking, and having undertaken, all activities required thereunder to Develop the Product and to file for and prosecute through to grant a Marketing Authorisation in the Territory for the Product for an indication within the Field. In particular:
- 4.6.1 Valneva or its Affiliate shall be, and shall take responsibility for all obligations imposed on, the Sponsor of the clinical trials required or undertaken for approval of the Product but, for the avoidance of doubt, will not be the Sponsor of any human challenge trial undertaken by a Third Party in connection with the Product;



- 4.6.2 if additional [\*\*\*] is required in excess of the funds [\*\*\*] pursuant to the [\*\*\*] Valneva shall be solely responsible at its sole cost for all additional funding of any further Development Activities (including any additional clinical trials) in order to obtain all necessary Regulatory Approvals for use and distribution of the Product in the Territory for an indication within the Field; and
- 4.6.3 for the avoidance of doubt, the Authority shall have no obligation to perform any acts or fund [\*\*\*] any activities under the Development Plan.

#### Marketing Authorisation Commitments

- 4.7 The Parties have agreed to seek such form of Marketing Authorisation as can:
- 4.7.1 most quickly be obtained from the relevant Regulatory Authority;
- 4.7.2 permits the placing on the market of the Product within the Territory for use within the Field; and
- 4.7.3 being the minimum approval required for the Orders,
- whether such Marketing Authorisation is subject to conditions or otherwise.
- 4.8 Valneva shall ensure that it (or its Affiliate) files an application for a Minimum Viable Marketing Authorisation for the Product with the Licensing Authority for the Territory for an indication within the Field at least as early as it files any other application for a Minimum Viable Marketing Authorisation for the Product with an indication within the Field anywhere else in the world, save that if the Licensing Authority for the Territory for the Product is the MHRA, [\*\*\*].
- 4.9 In respect of prosecuting the application for a Minimum Viable Marketing Authorisation for the Product in the Territory, Valneva shall use Commercially Reasonable Efforts to do so, which shall be no less than the same efforts it and its Affiliates use to prosecute to grant or issuance of a Marketing Authorisation for the Product anywhere else in the world. [\*\*\*] Should the Minimum Viable Marketing Authorisation issued be subject to conditions or other requirements specified by the Regulatory Authority or not be a full Marketing Authorisation, [\*\*\*].
- 4.10 [\*\*\*]:
- 4.10.1 [\*\*\*]
- 4.10.2 [\*\*\*].
- 4.11 Without prejudice to clauses 4.2 or 4.8, Valneva will adopt and implement a plan for obtaining the appropriate Minimum Viable Marketing Authorisation for the Product in the Territory. Such plan shall be in accordance with the Development Plan and shall be provided to the JSC (including any updates to it from time to time), and discussed by and will be updated to implement any reasonable changes to it proposed by the JSC. Valneva

shall file in its own name an application for such a Minimum Viable Marketing Authorisation for the Product in the Territory with the Licensing Authority for an indication in the Field.

4.12 Valneva shall:

- 4.12.1 use Commercially Reasonable Efforts to prosecute, secure and maintain any Minimum Viable Marketing Authorisation filed for the Product in the Territory for an indication in the Field; and
- 4.12.2 not withdraw any application for a Minimum Viable Marketing Authorisation) in respect of the Product in the Territory without the JSC's approval, unless required by Applicable Laws or the Licensing Authority;
- 4.12.3 not assign, transfer, lease or otherwise dispose of any application for or any granted or issued Regulatory Approval for the Product, which has been granted for or covers the Territory without the prior written consent of the Authority (not to be unreasonably withheld or delayed); and
- 4.12.4 secure and maintain all other Regulatory Approvals required in the Territory for the Development, Manufacture and supply to the Authority or its Authorised Agent of the Product in the Territory;

in each case in accordance with the Development Plan and the regulatory strategy plan required by clause 4.11. The foregoing obligations shall apply to an Affiliate holding the same, and shall continue to apply after the expiry or termination of this Agreement until expiry of the shelf life of all the Products Delivered to the Authority pursuant to this Agreement.

4.13 Valneva shall, and shall procure that its Affiliates and Subcontractors shall, comply with all requests and recommendations of the Licensing Authorities and any other Regulatory Authority in connection with the Product to be supplied in accordance with this Agreement and the Manufacture of such Product.

4.14 Valneva shall use either the [\*\*\*] or the [\*\*\*] or both in order to obtain the Marketing Authorisation in the Territory at the earliest possible date. [\*\*\*] Valneva shall ensure that the Minimum Viable Marketing Authorisation granted for the Territory will include the Facilities as facilities qualified and validated for Manufacture of the Product to be supplied to the Authority under this Agreement.

Variations to Marketing Authorisations

4.15 If Valneva (or its Affiliate) wishes to vary or amend any Marketing Authorisation (or any application for a Marketing Authorisation) for the Product in the Territory, or change the indications for the Product, or the Specification of the Product Valneva must notify the JSC in advance of such variation or amendment of the Marketing Authorisation or change to the indications or Specification and discuss and implement any changes reasonably required by the JSC in such process or activity, unless the same are contrary to any variation or amendment required by Applicable Laws or by a requirement of the Licensing Authority.

- 4.16 The obligations in clause 4.15 shall continue to apply after the expiry or termination of this Agreement until such time as, in accordance with clause 5.18, the Authority notifies Valneva in writing that it has used or disposed of all units of the Product supplied under this Agreement.

#### Loss of Regulatory Approvals

- 4.17 Valneva shall without undue delay inform the Authority in writing if it knows or believes there to be any delay to, rejection of, or other issue jeopardising the grant or renewal of the Minimum Viable Marketing Authorisation in the Territory. If the Minimum Viable Marketing Authorisation in the Territory is:

- 4.17.1 rejected, withdrawn or suspended by the Licensing Authority;
- 4.17.2 withdrawn or amended by Valneva (or its Affiliate) such that it no longer supports an indication within the Field; or
- 4.17.3 is not renewed by the Licensing Authority following its expiry;

and such decision or action (in the case of a Licensing Authority decision) is final and not capable of appeal or equivalent process, then (i) the Authority shall be entitled to terminate this Agreement with immediate effect upon written notice to Valneva; (ii) the Authority shall upon termination reimburse Valneva any amounts with respect to any Required Commitments or [\*\*\*] which have not previously been paid by the Authority and are Irrevocably Committed by Valneva; and (iii) clause 7.11 shall apply and the Net Funding shall be the relevant specified amount in such clause. Notwithstanding the foregoing, in the period following any Licensing Authority decision and prior to it becoming final, Valneva and the Authority shall agree a standstill pending that final decision such that Valneva shall not incur further costs or commitments for which the Authority would otherwise become liable for under this Agreement other than those for which the Authority gives its express consent.

#### Information Disclosures

- 4.18 Upon request by the Authority, Valneva shall respond to all reasonable enquiries and requests for information made by the Authority regarding the Development of the Product [\*\*\*]. Without prejudice to the foregoing, through the Project Managers and JSC, Valneva shall keep the Authority promptly informed of all material events and issues that impact the Development and/or Manufacture of the Product hereunder and its Delivery in accordance with the Delivery Schedule, including:

- 4.18.1 progress and performance of the Development Activities, the overall Development of the Product, and the progress towards achieving the Milestones in the Development Plan and meeting the timelines set out therein;
- 4.18.2 all data read outs, including interim data read outs, clinical trial protocol adjustments, adverse events, delays and other matters that may reasonably affect the safety, efficacy, approval, or timing of the studies or approval of the Product;
- 4.18.3 any clinical trial results of findings that impact the efficacy or safety of the Product;

4.18.4 establishment and operation of the Manufacturing infrastructure, including securing or losing capacity at Facilities, securing or delays in supply of raw materials and equipment supply, and the Production Schedule and any updates thereto;

4.18.5 any actual or anticipated delays in Delivery against, or updates to, the Delivery Schedule.

For the avoidance of doubt, any information disclosed subject to this clause 4.18 is subject to the confidentiality obligations set out in clause 20, it being acknowledged that (i) information to be provided in accordance with this clause may be price sensitive, and (ii) nothing herein shall limit a party's rights under the [\*\*\*].

4.19 Where reasonably requested by the Authority, Valneva shall provide the Authority with product information (including product photographs and descriptions) in such manner and upon such media as requested. Valneva grants the Authority a [\*\*\*].

#### Emergency Use Authorisation

4.20 The Parties acknowledge and agree that Valneva or the Authority may (but shall be under no obligation to), subject to JSC approval, apply for an Emergency Use Authorisation for the Product with the Licensing Authority for the Territory for use within the Field.

### **5. MANUFACTURE AND SUPPLY OF PRODUCT**

#### Manufacturing and Supply Commitment

5.1 Valneva shall Manufacture and supply the Product to the Authority, and the Authority shall purchase the Product, subject to and in accordance with the terms and conditions of this Agreement.

#### Manufacturing Plan

5.2 Valneva shall follow and implement the Manufacturing Plan in all material respects, including procuring that its Affiliates provide, the human and other resources, materials, facilities and equipment required for the Manufacturing Plan, and shall use Commercially Reasonable Efforts to do so in accordance with the Milestones and timelines set out therein.

5.3 The Manufacturing Plan at Schedule 6 and any update thereto shall:

5.3.1 set out details and estimated timelines for technology transfer, engineering and PPQ batches and the commercial Manufacture of the Product, provided that the Manufacturing Plan shall be adjusted and updated by Valneva (subject to requiring the JSC's consent insofar as any change or update affects a Milestone or is a material change or update) as Development progresses and the plans for Manufacture of Product will become more focused, specific and detailed;

5.3.2 be consistent with the provisions and objectives of this Agreement to deliver commercial supplies of Product in the Territory for an indication within the Field and in accordance with [\*\*\*] and the Delivery Schedule; and

- 5.3.3 not impose obligations on the Authority and/or Authority's Affiliates unless the Authority has agreed in writing to assume responsibility for such obligations.
- 5.4 Valneva shall be responsible at its own cost and expense for the Manufacture of the Product, the implementation and execution of the Manufacturing Plan and for undertaking, and having undertaken, all activities required thereunder to Manufacture the Product. For the avoidance of doubt, the Authority shall have no obligation to perform any acts or fund (other than any payments due under this Agreement and the [\*\*\*) any activities under the Manufacturing Plan.

Supply of Product

- 5.5 The Product shall be supplied by Valneva as finished and labelled drug product. The Parties agree that fill/finish shall be undertaken using the Solna Facility, unless otherwise agreed between them. Arrangements for the fill/finish shall be agreed between the Parties within the JSC and set forth in the Manufacturing Plan.
- 5.6 Where the capacity referred to in clause 5.5 is limited, Valneva shall use Commercially Reasonable Efforts to work with other CMOs within the Territory and Europe approved by the JSC. In the event the preceding options are not commercially viable, Valneva may build its own fill/finish facilities in the Territory, subject to Valneva securing funding (which may include funding from [\*\*\*) although there is no commitment or guarantee [\*\*\*) in that regard and [\*\*\*) would need to be subject to further agreement). In selecting CMOs, Valneva shall give regard as to the Product being fully inactive such that standard CMO procedures can be deployed.
- 5.7 Valneva shall:
- 5.7.1 maintain a properly documented system of quality controls and processes (including a quality management system) covering all aspects of its obligations under this Agreement (including those it may subcontract to others) and shall at all times comply with such quality controls and processes and not materially amend them without notifying the Authority of any change which can reasonably be seen to have an effect on the Authority or the approval or use of Product under this Agreement, in writing at least [\*\*\*) in advance of such material change (such notice to include the details of the consequences which follow such change being implemented); and
- 5.7.2 not make any changes to the Products which would require approval by a Regulatory Authority in the Territory without giving prior notice to the Authority of such changes and in good faith considering and implementing all reasonable requests made by the Authority in respect of such changes.

[\*\*\*)

- 5.8 Subject to clause 5.9, Valneva shall ensure that the volume of Product that is the subject of the Orders shall be supplied to the Authority in accordance with the obligations under clause 9. Furthermore, Valneva shall ensure that Product shall be supplied to the Authority on a [\*\*\*) basis, meaning that:

- 5.8.1 Valneva (a) will supply the Authority with Conforming Product in full to meet the total quantity required under the Initial Order [\*\*\*] and (b) [\*\*\*]; and
- 5.8.2 in respect of the [\*\*\*];
- (collectively [\*\*\*]). A worked example of the [\*\*\*] under this clause 5.8 is set out in Schedule 10.
- 5.9 If Valneva proposes to supply Product to a Third Party outside of the Territory before the grant or issuance of a Minimum Viable Marketing Authorisation for the Product in the Territory, then Valneva shall first notify the Authority of such decision and, notwithstanding clause 5.8, Valneva shall, at Authority's election, either (i) supply Product to the Authority pending grant of the Minimum Viable Marketing Authorisation in the Territory and in quantities in compliance with clause 5.8; or (ii) reserve and allocate for the Authority physical volumes of Product in quantities in compliance with clause 5.8 and hold the same for Delivery to the Authority immediately upon grant of the Minimum Viable Marketing Authorisation or earlier upon the Authority's written request. For the avoidance of doubt, the foregoing shall not apply to the Initial Order, which shall be supplied on a [\*\*\*] basis in accordance with clause 5.8.
- 5.10 Valneva shall, and shall procure that its Affiliates and Subcontractors shall, use Commercially Reasonable Efforts to expedite Manufacture and Delivery of the Initial Order and the Follow On Order to the Authority for the Territory, such efforts being no less than the efforts expended for Manufacture of the Product for any other territory or Third Party.

#### Product Conformance

- 5.11 Valneva shall procure that the Product to be supplied under this Agreement has been Manufactured (including being QP certified and released) in compliance with Applicable Laws, Applicable Standards, Good Industry Practice, Guidance, all batch records and the Marketing Authorisation in the Territory. Without limiting the foregoing, Valneva shall, and shall procure that its Affiliates and Subcontractors shall, exercise the same level of effort, diligence and care in the Manufacture and supply of the Product to the Authority hereunder as it would exercise in carrying out the same or substantially similar services on behalf of itself or for its Affiliates.
- 5.12 Valneva shall ensure that all Product supplied to the Authority (or its agent or designee) under this Agreement shall:
- 5.12.1 at the time of Delivery and until expiry of the Product's Minimum Shelf Life comply fully with the version of the Specification and the Marketing Authorisation in the Territory in effect as at the date of Delivery of the Product if stored under the specified conditions set out in the SmPC;
- 5.12.2 be free of any identifiable Non-Compliance and shall be unadulterated;
- 5.12.3 be labelled in accordance with the Marketing Authorisation and Applicable Laws and the Documentation accompanying such Product shall comply with the Product, in each case prior to or at the time of its Delivery;

- 5.12.4 have a minimum shelf life at the later of the time of Delivery to Authority and release for use in the Territory that is no less than the Minimum Shelf Life; and
- 5.12.5 be new and have not (i) previously left the control of Valneva or a Subcontractor of Valneva; or (ii) been rejected or returned by any other entity, or (iii) been reprocessed or reworked, in each case of (i), (ii) and (iii) prior to their supply to the Authority under this Agreement.
- 5.13 Valneva shall be solely responsible for the Manufacturing of the Product and its supply of Product to the Authority hereunder.
- 5.14 Valneva shall fully and promptly respond to all requests for information and/or requests for answers to questions regarding this Agreement, the Products, any complaints and any disputes at the frequency, in the timeframes and in the format as requested by the Authority from time to time (acting reasonably).

No Exclusive Purchasing Arrangement

- 5.15 Nothing in this Agreement shall amount to an exclusive purchasing obligation on the Authority or preclude or restrict the Authority from purchasing any products whatsoever from Third Parties, including any products that are complementary to, competitive to, equivalent to, or substitutable for the Product or that are indicated for or expected to be beneficial for use in the prophylaxis, treatment or vaccination against SARS-CoV-2.

Manufacturing At Risk

- 5.16 Without prejudice to the required payments to be made pursuant to this Agreement and the [\*\*\*], the Parties acknowledge that Valneva may be manufacturing the Product at risk ahead of securing the necessary Marketing Authorisation in order to maximise the earliest availability of the Product to the Authority.

Authority's Obligations

- 5.17 The Authority shall only supply the Product to Authorised Agents and Administering Entities that hold the necessary Regulatory Approval to, or are otherwise permitted under Applicable Laws to, receive the Product. Notwithstanding the foregoing, if the Authority has excess doses of Product, it shall, subject to the agreement (not to be unreasonably withheld or delayed) of Valneva, be entitled to donate or transfer such excess Product to any Third Party (including COVAX) that hold the necessary Regulatory Approval to, or are otherwise permitted under Applicable Laws to, receive the Product.
- 5.18 The Authority shall use Commercially Reasonable Efforts to notify Valneva in writing confirming that it has used or disposed of all units of the Product supplied under this Agreement.
- 5.19 The obligations in clause 5.17 shall continue to apply after the expiry or termination of this Agreement.

### Minimum Shelf Life

- 5.20 Valneva currently anticipates, [\*\*\*], that the Minimum Shelf Life to be achieved from stability studies [\*\*\*] from fill finish, and agrees to use Commercially Reasonable Efforts to [\*\*\*], as soon as reasonably practical, and shall use Commercially Reasonable Efforts to confirm the Minimum Shelf Life and report the same to the Authority by no later than [\*\*\*]. Notwithstanding the foregoing, Valneva shall ensure that at a minimum a remaining shelf life as set forth in clause 9.16 (and calculated from the date of Delivery) shall apply to all Products Delivered under this Agreement.

## 6. RAW MATERIALS STOCK, PRODUCTION SCHEDULES AND BUSINESS CONTINUITY

### Securing Materials Stock

- 6.1 Valneva shall, with effect from the Effective Date and throughout the Term, use Commercially Reasonable Efforts to build up, maintain and replenish an effective safety stock of Manufacturing materials (including raw materials) required for the Manufacture of the Product (“**Materials Stock**”), in order to ensure that Valneva, its Affiliates and their Subcontractors have sufficient materials and raw materials in order to meet the Delivery Schedule.
- 6.2 Valneva shall be responsible for and ensure that the Materials Stock shall be held in accordance with its storage conditions and GMP and shall operate an effective [\*\*\*] process to ensure Materials Stock is used within its shelf life. Following any reduction to or cancellation of the Order (in whole or part), or termination of this Agreement, on written notice from the Authority no later than [\*\*\*] from such reduction or cancellation and at the Authority’s cost, Valneva shall make available for collection by the Authority or its nominee of the Materials Stock held by or on behalf of Valneva where that Materials Stock has been purchased using Funds and will not be used for supply of the Product hereunder.

### Production Schedules

- 6.3 On a [\*\*\*] basis Valneva shall provide the Authority with the then most current and accurate production schedule for the Manufacture of Product that is the subject of this Agreement. Such production schedule should identify, for the Manufacture of Product:
- 6.3.1 key Materials Stock levels including shelf life;
  - 6.3.2 if and where applicable, Facility reservation schedules for Manufacturing activities, including pre-Manufacturing activities, commencement dates for Manufacturing, duration of reservation, cancellation rights including financial costs and penalties based on the date of cancellation;
  - 6.3.3 reservation facilities with Third Party providers and CMOs to the extent used in respect of Manufacture of the Product;
  - 6.3.4 testing, fill/finish, packaging, Labelling and release activities, including any facility reservations and details of any cancellation rights including financial costs and penalties based on the date of cancellation; and,
  - 6.3.5 anticipated Delivery dates;
- (collectively, clauses 6.3.2 to 6.3.5 being a “**Production Schedule**”).



- 6.4 Valneva shall structure and work to its Production Schedule such that it is able to meet the Delivery Schedule. Subject to clause 9.1, any variation to the Delivery Schedule must be via agreement with the JSC.

Business Continuity Plan

- 6.5 Valneva has and shall continue to develop, implement and keep current a reasonable risk management program for the Facilities, including a Business Continuity Plan, it being acknowledged that if there is a Business Continuity Event, it is unlikely that a Business Continuity Plan may not enable the Delivery Schedule to be met but it is designed and intended to minimise any delays to the Delivery Schedule. At the Authority's request, Valneva shall make a copy of the Business Continuity Plan available to the Authority, or its representatives, for review. The Business Continuity Plan shall detail reasonable strategies for responses to, mitigation of, and recovery from a range of reasonably foreseeable disruptive events applicable to the Facilities.
- 6.6 Valneva shall:
- 6.6.1 use Commercially Reasonable Efforts to ensure its Business Continuity Plan operates effectively with respect to the supply of the Products to the Authority in accordance with this Agreement;
  - 6.6.2 ensure its Business Continuity Plan provides for continuity during a Business Continuity Event and shall test its Business Continuity Plan at reasonable intervals or within such specific periods as may be agreed between the Parties taking into account the criticality of this Agreement to the Authority; and
  - 6.6.3 ensure that its Business Continuity Plan complies, on an ongoing basis, with any specific business continuity requirements, as may be discussed pursuant to the JSC.
- 6.7 For the avoidance of doubt, having a Business Continuity Plan and its implementation does not relieve Valneva from its Manufacturing and supply obligations under this Agreement.
- 6.8 Without limiting the obligations under clause 9.12, if for any reason related to the Facilities Valneva is unable to supply Conforming Product to Authority in accordance with the Delivery Schedule, then Valneva shall instead use Commercially Reasonable Efforts to source and supply Product from its other supply chain arrangements involved in the Manufacture of Product for countries outside the Territory and shall ensure that such Product sourced from those other facilities may be supplied hereunder as Conforming Product, it being acknowledged that any Product so supplied from any other facility will not comply with any requirement that the Product be manufactured at the Facilities, but that notwithstanding this such a Product will be regarded as a Conforming Product.

7. **GOVERNMENT [\*\*\*] PAYMENTS**

Provision of Government [\*\*\*] Payments

- 7.1 Subject to clause 7.3, the Government [\*\*\*] Payments shall be those amounts specified in Schedule 9.
- 7.2 The Authority shall, in accordance with the terms set out in this Agreement, [\*\*\*] the Government [\*\*\*] Payments to Valneva and upon written notice from Valneva specifying the amount, associated relevant Required Commitments and associated date for payment of such amount in accordance with Schedule 9.
- 7.3 If Valneva requires any [\*\*\*] amount by way of Government [\*\*\*] Payment in order to enter into any agreement or undertake any investment of a substantially similar nature to any Required Commitment:
- 7.3.1 Valneva shall notify the Authority via the JSC;
- 7.3.2 to the extent that:
- (a) [\*\*\*]; and
- (b) [\*\*\*],
- the Authority shall [\*\*\*] and shall, [\*\*\*].
- 7.4 Valneva:
- 7.4.1 has used Funds paid to it [\*\*\*] of this Agreement in compliance with Schedule 11;
- 7.4.2 shall comply with the terms and conditions set out in Schedule 11 with respect to any Funds paid to it;
- 7.4.3 shall ensure the Funds are used by Valneva solely for those specific and specified activities listed in Schedule 9;
- 7.4.4 shall only spend and/or commit the Funds according to the items and activities for such [\*\*\*] set out in Schedule 9, and shall use its Commercially Reasonable Efforts to ensure that any cancellation and refund policies applicable to such spend or commitment shall conform with the applicable descriptions in Schedule 9 or such other conditions agreed with the Authority in writing from time to time, according to customary practice in the pharmaceutical industry;
- 7.4.5 acknowledges that no Funds shall be deemed to have been paid to Valneva until immediately before Valneva is required to pay the relevant amount as contemplated in Schedule 9 and, in accordance with the drawdown process above at clause 7.1, the Authority transfers such amount to Valneva for the purposes of enabling Valneva to make such payment (the balance of any such Funds which will be held in a Valneva account pending payment being made by Valneva “**Consigned Amounts**”), those Consigned Amounts shall remain the property of, and be held on trust on behalf of, the Authority unless and until Valneva makes such payment in accordance with the terms of this Agreement. Valneva will establish an account outside its security arrangements, in which these monies and the [\*\*\*] shall be held, using Commercially Reasonable Efforts to do so as soon as reasonably practical and in any event within [\*\*\*];

- 7.4.6 shall keep the Authority promptly informed of all delays or issues concerning any of Required Commitments (or any associated land, goods, services or capacity reservations) for which the Funds are or will be used or allocated;
  - 7.4.7 shall co-operate with the Authority and constructively respond to all questions and enquiries regarding the use of Funds including Consigned Amounts, the timing of commitments and payments and to the extent cancellation and refund terms have been secured by Valneva for any orders, arrangements or agreements entered into in respect of spend or commitments using the Funds, it shall keep the Authority appraised of deadlines for the same;
  - 7.4.8 shall promptly provide receipts for, and evidence of, all spend, payments and commitments made using the Funds, and permit the Authority to audit, or have audited, its accounts and records concerning the use of the Funds;
  - 7.4.9 shall ensure, with respect to Authority Specific Commitments only, that all goods and services purchased, acquired or reserved using any of the Funds (directly, indirectly, in whole or in part) shall be held on trust for the Authority, but Valneva shall acquire such goods and services in its own name;
  - 7.4.10 shall, upon termination of this Agreement, immediately return to the Authority any Consigned Amounts (save to the extent the same may be necessary to discharge any Irrevocably Committed payment for which the Authority is liable upon such termination) and, to the extent not provided under clause 7.4.8 above, it shall provide receipts and/or reasonable evidence of, payments made to third parties for all other amounts of the Funds paid to Valneva and not returned to the Authority; and
  - 7.4.11 shall ensure that any Funds used, lost or otherwise spent other than in accordance with this Agreement shall be recoverable and payable to the Authority in full on demand by Valneva.
- 7.5 Valneva shall take Commercially Reasonable Efforts to mitigate any losses, costs or wastage in respect of the use of all payments of the Price made pursuant to clause 13, Government [\*\*\*] Payments and [\*\*\*].

#### Authority Specific Commitments

- 7.6 If Valneva:
- 7.6.1 undertakes or makes an Authority Specific Commitment; and
  - 7.6.2 in that regard enters into an agreement with any Third Party, for the purposes of making that Authority Specific Commitment (a “**Authority Related Agreement**” and the relevant goods will be “**Authority Related Goods**”);

should that Authority Related Agreement or any Authority Related Goods become redundant, or are otherwise not used for the purposes of this Agreement (in whole or part) for whatever reason, then on the Authority's request Valneva shall either:

- (a) transfer the Authority Related Goods or the benefit of any Authority Related Agreement to the Authority or its designee; or
- (b) if Valneva is able to reuse, resell or repurpose any relevant Authority Related Goods or reuse, resell or repurpose any services under an Authority Related Agreement, Valneva shall promptly pay to the Authority an amount equal to the value of such Authority Related Goods or under the Authority Related Agreement where it is able to reuse, resell or repurpose the goods or services.

Return of value from the Funds

- 7.7 From the Effective Date until the later of [\*\*\*] or the final delivery of Products to the Authority pursuant to the Follow On Order (if applicable) (the "**Final Date**"), any land, equipment, materials or services acquired or reserved using (in whole or part) the Funds or any funds or payments made pursuant to the arrangements listed under Schedule 9 ("**Relevant Assets**") shall:
- 7.7.1 only be used for the purposes of Valneva's project to manufacture the Product (initially pursuant to this Agreement) and not for any other purpose; and
  - 7.7.2 not, save by way of charge pursuant to Valneva's financing arrangements, be disposed of, sold, gifted, loaned, leased, destroyed or cancelled without the prior written consent or direction of the Authority.
- 7.8 Subject to clause 7.9, if, before the Final Date, any Relevant Asset becomes redundant, or is otherwise not used for the purposes of Valneva's project to manufacture the Product (including for the purposes of supply under this Agreement) for whatever reason, then to the extent it is reasonably possible without causing significant financial loss to Valneva, Valneva shall (including, where required, subject to and using Commercially Reasonable Efforts to secure the consent of any lender to Valneva who has any charge over such assets or any preferential right to receive the proceeds of any sale of any asset as a mandatory prepayment of debt), at the direction of the Authority, use Commercially Reasonable Efforts to:
- 7.8.1 deliver or make available the same to any Third Party, or
  - 7.8.2 repurpose or reuse the equipment, materials or services for alternative activities or projects, or
  - 7.8.3 seek refundable returns and cancellations of the same and/or re-sell the land, equipment, materials or services at prevailing market rates, and in the case of clause 7.8.2 or 7.8.3 Valneva shall pay (or deliver in another form of equivalent financial value) to the Authority the value of any refund or any proceeds from the sale received up to a maximum amount equivalent to all Funds or sums pursuant to the arrangements listed under Schedule 9 provided by the Authority to the extent that value is not otherwise recovered by the Authority pursuant to this Agreement (any value recovered by the Authority pursuant to this clause 7.8 being "**Authority Recoveries**").

- 7.9 If and to the extent that there are any Authority Recoveries such amount shall not be recovered through or discounted from payments for the price of Products under this Agreement. To the extent the Authority receives the benefit of such recovery or discount through payments for the Product supplied pursuant to this Agreement, the amount of any Authority Recovery will be reduced accordingly PROVIDED THAT if, notwithstanding this, Valneva transfers an amount of value pursuant to clause 7.8 and also provides such value to the Authority through a reduction in the price, the Authority must promptly pay to Valneva the amount of such value to prevent double recovery or shall apply such payment to any future Product delivered hereunder.
- 7.10 To the extent that, for any reason, the amounts recovered by the Authority pursuant to clauses 7.8 and 7.9 are less than the aggregate of the Government [\*\*\*] Payments, clause 7.11 shall apply and the shortfall shall be the relevant specified amount.
- 7.11 Where this clause 7.11 applies, the Authority shall be entitled to recover the relevant specified amount by way of [\*\*\*]. Valneva shall procure that such [\*\*\*] shall be binding on its Affiliates, and its licensees and successors in interest of such vaccines and [\*\*\*] facilities and activities.
- 7.12 Valneva will pay a royalty to the Authority on all sales [\*\*\*] of Product manufactured using the Facilities at a rate of [\*\*\*] of net sales of such Product, with a maximum royalty payable hereunder being EUR[\*\*\*]. Commencing with the first sale to a [\*\*\*]. Valneva shall issue royalty reports on a [\*\*\*] basis within [\*\*\*] of the end of the relevant [\*\*\*]. Such obligation shall continue until all royalties payable pursuant to this clause are paid. The Authority shall issue an invoice for the royalty due for such preceding [\*\*\*] which shall be paid by Valneva within [\*\*\*] (and the provisions of clause 14 shall apply mutatis mutandis to such payments). The Authority shall have the right on an [\*\*\*] basis to have a Third Party accountant audit all records applicable to net sales of the Product. Should the royalty be underreported by Valneva by more than [\*\*\*] in the applicable period then Valneva shall [\*\*\*]. Valneva shall procure that royalties shall be paid in respect of net sales by each of Valneva, its Affiliates, licensees and successors in interest of the Product.

## 8. ORDERING

### Initial Order

- 8.1 The form of written order for thirty (30m) million Regimens of the Product (the “**Initial Order**”) for Delivery in accordance with the Delivery Schedule is attached to this Agreement as Appendix 1. Immediately upon execution of this Agreement by the Parties, the Initial Order shall take effect on the terms of this Agreement.

### Follow On Order

- 8.2 During the Term, Authority shall have the right to submit to Valneva no later than [\*\*\*] a written order for up to a further twenty (20m) million Regimens of the Product for Delivery in accordance with the Delivery Schedule (the “**Follow On Order**”), together with the Authority’s order number, VAT number, and invoice address.

### Additional Orders

- 8.3 During the Term, the Authority shall have the right to submit to Valneva:
- 8.3.1 no later than [\*\*\*] a written order for [\*\*\*] and [\*\*\*] Regimens of the Product for Delivery during [\*\*\*];
  - 8.3.2 no later than [\*\*\*] a written order for [\*\*\*] and [\*\*\*] Regimens of the Product for Delivery during [\*\*\*]; and/or
  - 8.3.3 no later than [\*\*\*] a written order for [\*\*\*] and [\*\*\*] Regimens of the Product for Delivery during [\*\*\*],
- (each an “**Additional Order**”) together with the Authority’s order number, VAT number, and invoice address. A Delivery Schedule for each Additional Order shall be agreed between the Parties.

### Acceptance and Adjustment of Orders

- 8.4 Valneva shall accept the Follow On Order and each Additional Order in writing, and each of the Follow On Order and each Additional Order shall be binding upon the Parties and subject to the terms and conditions set out in this Agreement. All other terms and conditions (including any terms and conditions which the Authority purports to apply under any order, specification or other document attached to any order form) are hereby excluded.
- 8.5 During the Term, Authority may from time to time and by written notice increase or decrease the volume of Regimens of Product originally ordered pursuant to clauses 8.1 and 8.2 as follows:
- 8.5.1 in the case of an increase to either or both of the Initial Order or the Follow On Order:
    - (a) the increase shall be binding on the Parties subject to the agreement of Valneva, such agreement not to be unreasonably withheld and not to be withheld in any event if there is available capacity (being capacity at the Facilities which has not already been irrevocably reserved, prior to that date, by other customers of Valneva or is otherwise required in order to fulfil legally binding commitments to other customers of Valneva), and the Parties shall agree in good faith a revised Delivery Schedule for the additional Regimens of Product provided that Products Delivered to the Authority pursuant to such increased Order must, unless the Parties agree otherwise, be in quantities which are capable of being Delivered prior to [\*\*\*] in the case of an increase to the Initial Order, and prior to [\*\*\*] in the case of an increase to the Follow On Order;
    - (b) where the change increases the volume of Regimens of either the Initial Order or the Follow On Order, the total Price payable under this Agreement shall increase to reflect the increase in volume of Regimens and the Authority shall promptly pay any such increase in the Price to Valneva in accordance with clause 13;

- 8.5.2 subject to clause 8.5.3, in the case of a decrease to either of or both of the Initial Order or the Follow On Order:
- (a) such a decrease may be made:
    - (i) following any [\*\*\*] Loss of Supply (which will include for the avoidance of doubt [\*\*\*] which has not been promptly remedied by Valneva within [\*\*\*]); or
    - (ii) within [\*\*\*] of receipt of a [\*\*\*] pursuant to clause 13.7.5, if such notification indicates that the actual Follow On Order Price will [\*\*\*] of the Target Follow On Order Price; or
    - (iii) within [\*\*\*] of disclosure of read outs from the clinical studies following last dosing in each [\*\*\*] and [\*\*\*] of the studies, provided that (x) the foregoing shall not require Valneva to refund any Paid Amounts to the extent that they are Irrevocably Committed but otherwise shall reimburse any surplus of the Paid Amounts attributable to the decreased or cancelled quantities, and (y) the Authority shall reimburse Valneva in respect of any Irrevocably Committed but unrecovered costs associated with wastage or scrapped work in progress arising out of such decrease which shall include any Adjuvant Commitment for such decreased volumes (provided that such Adjuvant was only ordered after the JSC had been informed that the Adjuvant was to be used to formulate the Product), and (z) Valneva shall use Commercially Reasonable Efforts to mitigate any of the foregoing payments or any costs payable by the Authority as a consequence of such decrease;
  - (b) the Parties shall agree in good faith a revised Delivery Schedule for the remaining volumes of Regimens of Product to be Delivered and any revised payments to be made under this Agreement;
- 8.5.3 a decrease in the Initial Order or the Follow On Order, pursuant to clause 8.5.2, shall take effect only subject to the following:
- (a) Valneva will use Commercially Reasonable Efforts to mitigate the Cost of Product and Price of Product;
  - (b) the Parties shall, each acting reasonably and in good faith, first agree (i) any reduction in the Initial Order Price or the Follow On Order Price, as the case may be (taking account of the results of any mitigation taken pursuant to sub-clause (a) above), and (ii) the appropriate increase in the price per Regimen for the remaining order, provided that if any reduction in the Initial Order Price or the Follow On Order Price (as applicable) is not agreed or acceptable to the Authority, the Authority may withdraw its notice to decrease the Initial Order or the Follow On Order (as applicable) and such Order shall be unaffected;

- (c) where the decrease is due to a Loss of Supply:
- (i) due to an Other Government Intervention, the price per Dose shall be adjusted pursuant to sub-clause (b) above on the basis that Valneva is not required to forgo its entitlement to any Cost of Product amount, or repay any amount, in respect of the Product save to the extent provided for under clause 9.8 provided that (1) should any sums be paid or become payable to Valneva or its Affiliates in respect of those Products that are not delivered due to the Other Government Intervention, such sums shall be deducted from the price adjusted pursuant to sub-clause (b); and (2) should the Authority reorder the quantity of Product that was decreased as a consequence of the Loss of Supply, the price paid following the original adjustment under sub-clause (b) shall be re-adjusted having regard to the total volume of Product supplied and subsequently reordered;
  - (ii) in circumstances other than sub-clause (c)(i) above, then there shall be no adjustment to the Price per Dose (pursuant to sub- clauses (b) or (c)(i) above) for any Product that remains subject to Orders despite the reduction in volume and such Price shall be determined as if the full volume of Product continued to be the subject of a binding Order; and
  - (iii) in all circumstances, Valneva shall use Commercially Reasonable Efforts to mitigate the Price payable for the portion of the Products that are supplied notwithstanding the Loss of Supply;

8.5.4 following any change in accordance with the foregoing, each of the Orders shall thereafter reflect the new volume of Product adjusted according to this clause.

## 9. DELIVERY

### Delivery Schedule

- 9.1 The delivery schedule, setting forth the quantities and timing of Delivery of the Regimens of Product pursuant to the Initial Order, is set out in Schedule 7 (as updated pursuant to this Agreement, the “**Delivery Schedule**”). The Delivery Schedule at Schedule 7 at the Effective Date is an interim outline schedule and Valneva shall, in good faith, finalise a more granular initial Delivery Schedule for the Initial Order to be agreed by the JSC within [\*\*\*] of yields, clinical and regulatory intelligence becoming available, and share elements of a more detailed Delivery Schedule (which shall reflect the principles in Schedule 7) with the JSC on a regular basis. Valneva shall use Commercially Reasonable Efforts to Deliver Products in accordance with the Delivery Schedule but it is acknowledged by the Parties that product development and launch is subject to inevitable uncertainties and so if, having used Commercially Reasonable Efforts, Valneva is unable to achieve the Delivery Schedule, the Delivery Schedule shall be adjusted following consultation and agreement (which agreement shall not be unreasonably withheld or delayed) with the JSC as may be reasonably appropriate provided that (i) the Delivery Schedule; and (ii) Valneva’s actual delivery of Product must at all times conform with [\*\*\*]; and any revised Delivery Schedule shall be set as close in time to the original Delivery Schedule as reasonably possible. If the Delivery Schedule needs to be updated



in accordance with this clause 9.1, Valneva shall notify the JSC of the necessary changes to the Delivery Schedule and the reasons therefor, and the JSC by agreement (which agreement shall not be unreasonably withheld or delayed) shall update the Delivery Schedule accordingly provided that it shall be reasonable for the Authority to withhold consent if the Delivery Schedule is extended for the Initial Order beyond [\*\*\*].

9.2 The Delivery Schedule may only be updated and refined during the Term in accordance with clause 9.1 or with the agreement of the JSC.

#### Authority's Authorised Agents

9.3 If the Authority wishes to appoint any Authorised Agents to act on the Authority's behalf in relation to part or all of this Agreement, including to receive one or more Deliveries of any Product (or part thereof):

9.3.1 the Authority shall notify Valneva in writing in advance;

9.3.2 the Authority shall ensure that any such Authorised Agent is a Health Service Body holding all necessary Regulatory Approvals to undertake the functions assigned to it and the appointment of such Authorised Agent and making of any Deliveries of any delivery of any Product (or part thereof) does not result in any increase in any liability of Valneva in respect of the production, sale, distribution and use of such Product; and

9.3.3 Valneva shall work and co-operate reasonably with each Authorised Agent appointed by the Authority upon such notification, and the Authority shall procure that such Authorised Agent works and co-operates reasonably with Valneva in relation to the same.

#### Delivery

9.4 Valneva shall:

9.4.1 deliver the Product [\*\*\*] at the Delivery Location ("**Delivery**" or "**Delivered**") with Delivery being complete upon the Product being unloaded and delivered into the cold chain storage facilities at the Delivery Location;

9.4.2 ensure that the total volume of Regimens set forth in the Order (as may be amended) shall be Delivered;

9.4.3 ensure that Delivery of Product (other than any replacement Product following a rejection of non-Conforming Product) shall not be made earlier than:

- (a) the date of grant or issuance of a Marketing Authorisation for the Product in the Territory, unless (i) Delivery is requested earlier by the Authority, and the Authority and Valneva agree on terms for the supply of Product under quarantine or (ii) an Emergency Use Authorisation is issued for the Product in which case Delivery may, upon the Authority's request, be made prior to the grant or issuance of the Marketing Authorisation; and

(b) the applicable dates set forth in the Delivery Schedule without the prior written consent of the Authority.

Any Delivery (or attempted Delivery) of Product earlier than the applicable date set forth in the Delivery Schedule or before grant/issuance of a Marketing Authorisation (unless requested earlier by Authority) may be accepted or rejected (in whole or part) by the Authority at its sole discretion and any rejection shall be at Valneva's sole risk, cost and liability and Valneva shall remain responsible for effecting the subsequent Delivery of Conforming Product in accordance with the Delivery Schedule and provisions of this clause 9.4.

9.5 Valneva may deliver the Product by separate instalments, provided however, that Valneva shall supply and Deliver Conforming Product (i) pursuant to [\*\*\*]; and (ii) in the quantities specified and (subject to clause 9.1) in accordance with timings set forth in the Delivery Schedule. Notwithstanding the foregoing, Valneva shall not be in breach of the foregoing obligation to comply with the Delivery Schedule if:

9.5.1 there is a material delay in Valneva securing the Marketing Authorisation for the Product in the Territory provided that (i) Valneva has complied with its obligations under clauses 4.7, 4.8, 4.9, 4.11 and 4.12; and (ii) delay was not caused by the breach of this Agreement;

9.5.2 there is any minor variance of dates of Delivery compared to the Delivery Schedule of up to [\*\*\*] due to the unpredictable nature of the Manufacturing of the Products, so long as such variance is agreed with the Authority in writing at least [\*\*\*] prior to the scheduled Delivery date for such Products as set out in the Delivery Schedule (a "**Grace Period**"); or

9.5.3 the Parties agree, from time to time and by mutual consent, to vary the Delivery Schedule;

provided however that Valneva has and shall continue to use Commercially Reasonable Efforts to procure supply and Delivery of Conforming Product in accordance with (i) [\*\*\*], and (ii) the Delivery Schedule and failing that as soon as possible outside of the timelines set forth in the Delivery Schedule. If Delivery of Product is delayed by more than [\*\*\*] from the date scheduled in the Delivery Schedule allowing for any applicable Grace Period, then the Authority may on written notice cancel (for a full and prompt refund) that quantity of Product which is late in accordance with clause 9.9.

#### Delays and Loss of Supply

9.6 Valneva shall promptly notify the JSC in writing of any actual or anticipated delay or change to the Delivery Schedule or any actual or anticipated delay in Delivery of Product against the Delivery Schedule, and shall use Commercially Reasonable Efforts to provide at least [\*\*\*] prior written notice to the JSC of any actual or anticipated delay or change.

9.7 If the Authority's supply is interrupted, delayed or deferred due to (i) any intervention by a government other than the Crown (an "**Other Government Intervention**"); (ii) demands or obligations from funders or other parties or entities; or (iii) commitments accepted by Valneva; (collectively a "**Loss of Supply**") and such Loss of Supply is not promptly remedied by Valneva within [\*\*\*], then in either case, the Authority may:

9.7.1 terminate or decrease all or part of its Orders to the extent not then delivered, but with the right to re-order the terminated or decreased amount at the same Product pricing terms (reflecting clause 8.5.3(c)), and with such re-order being (at the Authority's election) for Delivery during the period specified in the original Order or such other Delivery schedule as reasonably agreed between the Parties; and/or

- 9.7.2 elect, by written notice served on Valneva within [\*\*\*] from the end of the [\*\*\*] period referenced above, not to provide any further funding (whether under this Agreement or the [\*\*\*]) other than paying the Price for any ongoing Orders.
- 9.8 In the event of a Loss of Supply:
- 9.8.1 where the Loss of Supply is caused by an Other Government Intervention under clause 9.7(i) above, the Authority shall be entitled (on behalf of the Crown including under the [\*\*\*]) to stop payment of, and recoup the [\*\*\*], Government [\*\*\*] Payments and any other amounts paid to Valneva pursuant to this Agreement to the extent:
- (a) they are not Irrevocably Committed; and/or
  - (b) [\*\*\*];
- and in each case to the extent the Authority has not previously received value in respect of the same through supply of Conforming Product hereunder. Notwithstanding the foregoing, the Authority will continue, on the terms of this Agreement, to pay the Price for any quantity of the Product which remains the subject of a continuing Order (as adjusted), notwithstanding the Loss of Supply, pursuant to clause 13; and
- 9.8.2 where the Loss of Supply is caused by an unremedied breach by Valneva of its obligations under this Agreement, the Authority shall be entitled to recover damages from Valneva and (to the extent not covered by damages but taking account of the benefits received by the Authority under this Agreement) funding provided by the Authority to Valneva under this Agreement or the [\*\*\*] and the Authority shall be entitled (on behalf of the Crown including under the [\*\*\*]) to stop payment of any further Government [\*\*\*] Payments or [\*\*\*], but will continue, on the terms of this Agreement, to pay the Price for any quantity of the Product which remains the subject of a continuing Order (as adjusted) pursuant to clause 13.
- 9.9 Where an Order for the Delivery of Product is late and outstanding such that Product has not been Delivered (other than due to Loss of Supply or as a consequence of Force Majeure) by more than [\*\*\*] from the date of Delivery in the applicable Delivery Schedule (allowing for any applicable Grace Period) then the Authority shall be entitled to terminate or reduce such outstanding volume of Product prior to its Delivery upon written notice to Valneva. Upon such notice, Valneva shall reduce or refund (as applicable) the Price payable or paid for such Order by a pro-rated amount equivalent to the Price for the applicable Order attributable to such terminated or reduced volume.

### Handling following Delivery.

- 9.10 The Authority or its Authorised Agent shall arrange for it or its nominated agent to be at the Delivery Location (ready for the Product to be unloaded) on the day of Delivery. Delivery shall be deemed complete upon the Product being unloaded and delivered into the cold chain storage facilities at the Delivery Location.
- 9.11 All Deliveries of the Product supplied hereunder shall, at the time of Delivery or reasonably in advance of the Delivery of the Product, be accompanied by the documentation specified in Schedule 8 (the “**Documentation**”).

### Mitigations for Capacity Limitations

- 9.12 Notwithstanding Valneva’s obligations to procure and manage Materials Stock, if Valneva, its Affiliates or any Subcontractor experience material capacity limitations or shortages of the Product or a material shortfall in bulk drug substance and/or other raw materials, ingredients, components, consumables and other materials (including Labelling and packaging materials) which are to be used for the Manufacture of the Product, where, in each case, such capacity limitation or shortfall will have an adverse impact on the Delivery Schedule or the supply of the Product in accordance with this Agreement more generally, Valneva shall promptly inform the JSC and the JSC shall discuss in good faith the reasons for such limitations and how to resolve such issues.
- 9.13 Notwithstanding clause 9.12, Valneva shall ensure that the Authority continues to receive [\*\*\*] of the Product, and shall use Commercially Reasonable Efforts to procure Product supplies necessary to meet the Orders and the needs of the UK population.
- 9.14 Valneva shall use Commercially Reasonable Efforts to ensure that Delivery of the Product in each case is made in accordance with the Delivery Schedule. If it transpires that Valneva are able to deliver the Product earlier than prescribed in the Delivery Schedule, Valneva shall promptly inform the JSC and the Authority of its revised Delivery date. The Authority (acting reasonably and in good faith) shall, within [\*\*\*] of receipt of such notification, confirm to Valneva and the JSC if it is willing to accept Delivery in accordance with Valneva’s revised Delivery date. Subject to such confirmation, the JSC shall discuss in good faith how the Delivery Schedule can be updated to allow Valneva to Deliver the Product in accordance with its revised Delivery date. In any event, Delivery of the Initial Order and the Follow On Order shall to the extent necessary to meet the requirements for [\*\*\*] be no slower or later than deliveries made to other territories from the Facilities or other production facilities.
- 9.15 For the avoidance of doubt, without prejudice to any other provisions of this clause 9, Valneva shall be considered, as of [\*\*\*], to be in material breach of its obligation to Deliver Product in accordance with the Delivery Schedule where it Delivers less than [\*\*\*] prior to [\*\*\*] unless [\*\*\*] is Delivered [\*\*\*].
- 9.16 Valneva shall ensure that Product is Delivered with a shelf life of [\*\*\*], provided that the Product is stored under the specified storage conditions according to the SmPC.

## 10. **RISK AND TITLE**

- 10.1 Risk of loss or damage and title to Products supplied under this Agreement shall pass to the Authority [\*\*\*] pursuant to clause 9.4.1, free and clear of any security interest, lien, charge or other encumbrance. Risk of loss or damage to Materials Stock shall remain with Valneva.

## 11. INSPECTION AND REJECTION OF PRODUCT

### Inspection & Rejection

- 11.1 Upon the later of Delivery of the Product and receipt of the Documentation, the Authority will inspect the external packaging of the Product and review the Documentation, and notify Valneva in writing (within [\*\*\*] of the Delivery of the Product and receipt of the Documentation) if it has identified a Non-Compliance and therefore rejects the Product (“**Rejected Product**”). Valneva agrees that the whole of any Delivery batch of Product may be rejected if a reasonable sample of the Products taken indiscriminately from that Delivery batch is found to have a Non-Compliance whereupon all Products from that Delivery batch shall be deemed Rejected Product. In such cases, the Parties shall enter into discussions in good faith to resolve any issues arising in connection with such Rejected Product.
- 11.2 Notwithstanding the above:
- 11.2.1 if a Non-Compliance in the Product was not reasonably ascertainable from a visual inspection of the Product and review of the accompanying Documentation; or
- 11.2.2 any Non-Compliance was latent or hidden;
- then such [\*\*\*] period shall not apply, provided that the Authority notifies Valneva in writing of its subsequent detection of the Non-Compliance within [\*\*\*] of the time the Authority first becomes aware of a Non-Compliance in the applicable Product (which may be prior to conducting root cause analysis) whereupon such Product shall be deemed a Rejected Product. Should the Authority notify Valneva pursuant to this clause 11.2, the Authority shall make available for collection by Valneva samples of the Rejected Product to Valneva (or its nominated agent) for collection and testing.

### Independent Laboratory

- 11.3 In the event of a disagreement concerning whether Product has any Non-Compliance or is Conforming Product, Valneva shall notify the Authority of such disagreement within [\*\*\*] of its receipt of the Authority’s notice of such Rejected Products. Valneva and the Authority shall use their respective reasonable endeavours to resolve such disagreement as promptly as possible. Either Party may submit a sample of the Product alleged to have a Non-Compliance for testing to an independent testing laboratory of recognised standing in the industry (to be mutually agreed and approved by the Parties acting in good faith) (“**Laboratory**”), to determine whether or not such Product was Non-Compliant or Conforming Product at the time of Delivery. The findings of the Laboratory shall be final and binding on the Parties other than in the event of manifest error. The cost of the testing and evaluation by the Laboratory shall be borne by the Party whose position is found by the Laboratory to have been erroneous.

12. **REMEDIES AND MITIGATION OF LOSSES**

- 12.1 Valneva acknowledges the critical importance that the Authority places on ensuring that Products are delivered free of Non-Compliance, in conformance with clauses 5.11 and 5.12, and in accordance with [\*\*\*] and the Delivery Schedule.

Rejected Product

- 12.2 In respect of any Rejected Product, provided that the Authority notifies Valneva of such Non-Compliance in accordance with clause 11.1, upon such Rejected Product being made available for collection by Valneva or resolution of any disagreement as to whether or not the Rejected Product is Non-Compliant in accordance with clause 11.3, Valneva shall [\*\*\*]:

12.2.1 [\*\*\*]

12.2.2 [\*\*\*].

Where it has been agreed or determined in accordance with clause 11 that the Rejected Product is Non-Compliant, the Rejected Product shall be made available for collection and disposal by Valneva, which Valneva shall collect in accordance with Applicable Law and at Valneva's sole expense and risk. Valneva shall be responsible for [\*\*\*] in respect of such Rejected Product.

Failure to Deliver Conforming Product

- 12.3 Save as specifically provided for in clause 22 of this Agreement, nothing in this Agreement shall limit or exclude Authority's remedies or rights in the event that Valneva fails to supply Conforming Product pursuant to this Agreement.

Obligation to Mitigate

- 12.4 In relation to any cancellation or termination of the Order (or this Agreement) or any other loss or liability that may arise:

12.4.1 Valneva shall use Commercially Reasonable Efforts to mitigate any losses that it may suffer or for which the Authority may have to pay for; and

12.4.2 the Authority shall use Commercially Reasonable Efforts to mitigate any losses that it may suffer or for which Valneva is or may be required to refund the Authority in accordance with this Agreement.

13. **PRICE, CHARGES AND DISCOUNTS**

Initial Order Price

- 13.1 Valneva shall supply the quantity of Product to Authority pursuant to the Initial Order at a Price, subject to clause 13.7, [\*\*\*] (the "**Initial Order Price**").

- 13.2 For the purposes of clause 13.1, the Parties have agreed that, subject to clause 13.11:
- 13.2.1 the Initial Order Price will be GBP [\*\*\*], representing a price per Dose of [\*\*\*] (as calculated in the estimate scheduled to this Agreement at Schedule 14) (“**Target Initial Order Price**”);
  - 13.2.2 the Cost of Product in relation to the Initial Order will be GBP [\*\*\*];
  - 13.2.3 the Adjuvant Cost in relation to the Initial Order will be GBP [\*\*\*];
  - 13.2.4 the aggregate of the Government [\*\*\*] Payments will be GBP [\*\*\*] (“**Target Government [\*\*\*] Payments**”); and
  - 13.2.5 the Target [\*\*\*] will be GBP [\*\*\*];
  - 13.2.6 the Target [\*\*\*] will be GBP [\*\*\*];
  - 13.2.7 the [\*\*\*] in relation to the Initial Order will be GBP [\*\*\*].

Instalment Payments for Initial Order

- 13.3 The Authority will pay to Valneva an amount equal to [\*\*\*] against receipt of an invoice for the same issued by Valneva after the following dates:
- 13.3.1 the date [\*\*\*];
  - 13.3.2 the date [\*\*\*];
  - 13.3.3 the date [\*\*\*];
  - 13.3.4 the date [\*\*\*]; and
  - 13.3.5 the date [\*\*\*].
- 13.4 There shall be deducted from the payments referred to in clause 13.3:
- 13.4.1 from the [\*\*\*] of the Target Government [\*\*\*] Payments
  - 13.4.2 from the [\*\*\*]:
    - (a) [\*\*\*] of the Target Government [\*\*\*] Payments; and
    - (b) [\*\*\*] of the Target [\*\*\*];
  - 13.4.3 from the [\*\*\*]:
    - (a) [\*\*\*] of the Target Government [\*\*\*] Payments; and
    - (b) [\*\*\*] of the Target [\*\*\*];
  - 13.4.4 from the [\*\*\*]:
    - (a) [\*\*\*] of the Target Government [\*\*\*] Payments; and

(b) [\*\*\*] of the Target [\*\*\*].

Follow On Order Price

13.5 For the Follow On Order (if applicable):

13.5.1 The Follow On Order Price shall be the aggregate of the Cost of Follow On Order [\*\*\*] relating to the Follow On Order.

13.5.2 Valneva has estimated that the Follow On Order Price will be approximately GBP [\*\*\*] per Dose (as calculated in the estimate scheduled to this Agreement at Schedule 15).

13.5.3 Valneva shall [\*\*\*] refresh its estimate of the Follow On Order Price and notify the Authority on or before the [\*\*\*] of the Follow On Order Price for the Follow On Order (the “**Target Follow On Order Price**”).

13.5.4 The Authority shall pay to Valneva against an invoice issued for:

(a) [\*\*\*] Target Follow On Order Price [\*\*\*];

(b) [\*\*\*] Target Follow On Order Price [\*\*\*]; and

(c) [\*\*\*] Target Follow On Order Price [\*\*\*].

Additional Order Price

13.6 For each Additional Order (if applicable) Valneva shall supply the quantity of Product to Authority pursuant to the Additional Order at a price per Dose equivalent [\*\*\*] (the “**Additional Order Price per Dose**”).

Target Price and [\*\*\*] Pricing

13.7 Notwithstanding the provisions of clauses 13.1, 13.2, 13.5, 13.6, 13.11 or 13.12:

13.7.1 Valneva shall use Commercially Reasonable Efforts to achieve an Initial Order Price payable under this Agreement per Dose at a level not to exceed the per Dose price [\*\*\*] Target Initial Order Price and calculated as [\*\*\*];

13.7.2 Valneva shall use Commercially Reasonable Efforts to mitigate and reduce the Cost of Product and the Cost of Follow On Order and in particular the Adjuvant Cost and Valneva shall make Commercially Reasonable Efforts to perform its obligations under and shall not amend in a manner which adversely impacts the Product, the Price or the Authority’s rights under this Agreement, or terminate the [\*\*\*] without the Authority’s consent (such consent not to be unreasonably withheld or delayed); and

13.7.3 Valneva shall regularly monitor and promptly notify the Authority if it calculates or reasonably anticipates that the Initial Order Price [\*\*\*]. If, following such notification, the Initial Order Price [\*\*\*], Valneva shall each time notify the Authority [\*\*\*] such notification [\*\*\*] shall provide Valneva’s [\*\*\*], calculated in good faith [\*\*\*] on an open book basis, of the revised Initial Order Price providing the details for such increase.



13.7.4 If:

- (a) [\*\*\*] indicates that the Initial Order Price will [\*\*\*] of the [\*\*\*]; and
- (b) the Authority [\*\*\*], then the Authority shall notify Valneva, within [\*\*\*] of receiving the relevant [\*\*\*] and this Agreement will terminate and sub-paragraphs (ii) and (iii) of clause 4.17 shall apply provided that in no circumstances shall the Authority be obliged to reimburse costs paid, incurred or committed by Valneva to the extent in aggregate such costs exceed [\*\*\*] Initial Order Price or a [\*\*\*] of the Initial Order Price [\*\*\*] by the Authority in accordance with this clause; or
- (c) the Authority [\*\*\*], then the Authority may notify Valneva within [\*\*\*] of receiving the relevant [\*\*\*] and clause 35.5.4 shall apply.

13.7.5 Valneva shall regularly monitor and promptly notify the Authority if it calculates or reasonably anticipates that the Follow On Order Price [\*\*\*]. If, following such notification, the Follow On Order Price [\*\*\*], Valneva shall notify the Authority [\*\*\*] such notification [\*\*\*] shall provide Valneva's [\*\*\*], calculated in good faith [\*\*\*] on an open book basis, of the revised Follow On Order Price providing the details for such increase.

#### Additional Order Payment Terms

13.8 For each Additional Order (if applicable) the Authority will pay to Valneva an amount of the aggregate Price (calculated pursuant to clause 13.5 or 13.6, as applicable) of the Products to be delivered pursuant to such Order invoiced on each of the following dates:

13.8.1 [\*\*\*];

13.8.2 [\*\*\*]; and

13.8.3 [\*\*\*].

#### Price Calculation

13.9 All costs associated with the Manufacture, supply and Delivery of Product, and Valneva's obligations hereunder, are included in the Price of each Product and, accordingly, Valneva shall perform its obligations under this Agreement at its cost and expense, without further reimbursement from the Authority beyond the Price.

13.10 Valneva shall calculate and charge the Price (including the Cost of Product) in good faith [\*\*\*] on an open book basis and provide transparency to the Authority as to the calculation of the same.

Deviations and Reconciliations in respect of the Initial Order, Follow On Order and Additional Orders

- 13.11 Within [\*\*\*] of the Final Payment Date the Parties shall calculate the Initial Order Price.
- 13.12 If:
- 13.12.1 the Initial Order Price exceeds the Target Initial Order Price Amount, the Authority shall pay such excess to Valneva; or
- 13.12.2 the Initial Order Price is less than the Target Initial Order Price, Valneva shall pay such shortfall to the Authority;
- in either case, within [\*\*\*] of the later of the Final Payment Date or completion of the calculation pursuant to clause 13.11.
- 13.13 Within [\*\*\*] of the date of payment of the final instalment made in accordance with clause 13.5.4(b) the Parties shall calculate the Follow On Order Price.
- 13.14 If:
- 13.14.1 the Follow On Order Price exceeds the Target Follow On Order Price Amount, the Authority shall pay such excess to Valneva; or
- 13.14.2 the Follow On Order Price is less than the Target Follow On Order Price, Valneva shall pay such shortfall to the Authority;
- in either case, within [\*\*\*] of the later of the date of payment of the final instalment made in accordance with clause 13.5.4(b) or completion of the calculation pursuant to clause 13.13.
- 13.15 Any adjustments in accordance with clauses 13.12 to 13.13 shall be exclusive of VAT such that any payment to or repayment by Valneva shall in each case be exclusive of VAT which shall be paid in addition thereto.

Currency

- 13.16 The Price payable by the Authority under this Agreement shall be payable in GBP. For the purposes of calculating the Initial Order Price and the Follow On Order Price where items are paid by Valneva in a currency other than GBP, for the purposes of this clause 13 such items shall be converted into GBP on a [\*\*\*] basis in conjunction with Valneva's internal [\*\*\*] reports at a rate from a reputable source or an average of rates from a reputable source taken at an appropriate time or times and having regard to the agreed principle that neither the Authority or Valneva should in real terms suffer a loss or receive a benefit as a result of currency conversions, except that in the case of each payment for Adjuvant the amount of such payment shall be converted at the rate actually obtained by Valneva to fund such payment and otherwise at a rate from a reputable source as at the date of such payment.

Audit Rights

- 13.17 Upon written notice on one occasion in respect of [\*\*\*], after completion of the relevant reconciliation, the Authority may appoint an independent accountancy firm to audit Valneva's and its Affiliates books and accounts with respect to the calculation of the Price

and the Cost of Product charged and incurred by Valneva in connection with the Manufacture, supply and Delivery of Conforming Product hereunder. Upon such notice, Valneva shall and shall procure that its Affiliates shall permit such accountancy firm to undertake such audit and shall co-operate and provide such information and access to its records as may be reasonably requested by the accountancy firm.

13.18 If following any audit the accountancy firm determines that the Price charged has been incorrectly calculated:

13.18.1 resulting in the Authority paying a higher sum than the Price for which Valneva is actually entitled under this Agreement then Valneva shall promptly within [\*\*\*] refund such overpayment to the Authority together with interest calculated in accordance with the rate set forth in clause 14.5 from the date the overpayment was made by the Authority until the date the overpayment is refunded to the Authority; or

13.18.2 resulting in Valneva being paid a sum less than the Price for which Valneva is actually entitled under this Agreement then the Authority shall promptly within [\*\*\*] pay to Valneva such shortfall.

#### No adverse pricing

13.19 Prior to completion of the Delivery of the Initial Order or any Follow On Order, Valneva shall not charge any Third Party or other government a price per Dose (including after any discounts, rebates or other direct or indirect pricing adjustment mechanisms) that is in aggregate more favourable to the Third Party or government than the Price charged (including any reconciled Price) or offered to the Authority, unless otherwise agreed with the Authority. [\*\*\*]

## 14. **INVOICING AND PAYMENT**

### Invoicing

14.1 Valneva shall invoice the Authority on each of the dates specified in clauses 13.3 and for each of the amounts payable thereon.

### Payment Terms

14.2 The Authority shall pay each invoice properly submitted in accordance with this Agreement within [\*\*\*] after the date of the applicable invoice.

14.3 All payments due to Valneva under this Agreement:

14.3.1 are exclusive of any VAT which may be chargeable, which if properly chargeable the Authority shall pay in addition at the rate and in the manner for the time being prescribed by Applicable Law and subject to Valneva providing a valid and accurate VAT invoice;

14.3.2 shall be made by the Authority by transfer to such UK bank account as Valneva may from time to time notify in writing to the Authority; and

14.3.3 shall be made in full and cleared funds, subject to any deduction or withholding which must be made under Applicable Laws.

#### Disputes and Late Payments

- 14.4 Where Authority raises a query with respect to an invoice, the Parties shall liaise with each other and agree a resolution to such query within [\*\*\*], of the query being raised. If the Parties are unable to agree a resolution within [\*\*\*] the query shall be referred to dispute resolution in accordance with the dispute resolution procedure prescribed in this Agreement. For the avoidance of doubt, the Authority shall not be in breach of any of its payment obligations under this Agreement in relation to any queried or disputed invoice sums unless the process referred to in this clause 14.4 has been followed and it has been determined that the queried or disputed invoice amount is properly due to Valneva and the Authority has then failed to pay such sum within a reasonable period following such determination.
- 14.5 If the Authority fails to pay any amount payable under this Agreement by the due date for payment, then without prejudice to any other rights or remedies that Valneva may have interest shall accrue on that amount in accordance with the Late Payment of Commercial Debts (Interest) Act 1998.
- 14.6 Without prejudice to clause 30, Valneva shall answer queries raised by the Authority regarding the calculation of Valneva's Cost of Product within a reasonable period of time and shall provide such information as the Authority may reasonably request in connection with such queries.

#### **15. WARRANTY AND UNDERTAKINGS**

- 15.1 As at the Effective Date, Valneva warrants to the Authority that:
- 15.1.1 it has the right and authority to enter into this Agreement and that it has the capability and capacity to fulfil its obligations under this Agreement;
  - 15.1.2 it is a properly constituted limited liability company and that it is fully empowered by the terms of its constitutional documents to enter into and to carry out its obligations under this Agreement and the documents referred to therein;
  - 15.1.3 there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of Valneva;
  - 15.1.4 there are no material agreements existing to which Valneva is a party which prevent Valneva from entering into this Agreement;
  - 15.1.5 all necessary actions to authorise the execution of and performance of its obligations under this Agreement have been taken before such execution;
  - 15.1.6 the Target Initial Order Price in clause 13.2 is reasonable and a genuine estimate that has been prepared in good faith and with reasonable skill and care and is not expected to be materially different from the actual Price charged for the Initial Order Price;

- 15.1.7 Valneva Scotland Ltd and Valneva have entered into a legally binding agreement with [\*\*\*] (a copy of which has been provided to the Authority) for the supply of the Adjuvant for the Product to be supplied hereunder (the “[\*\*\*]”); and
- 15.1.8 the purchase of OB2 has completed and Valneva is the owner of the land at OB2 and is in the process of obtaining all necessary consents and licences to construct and fit out the facility at such site.
- 15.2 As at the Effective Date, the Authority warrants to Valneva that:
- 15.2.1 it has the right and authority to enter into this Agreement;
- 15.2.2 it is fully empowered to enter into and to carry out its obligations under this Agreement and the documents referred to therein;
- 15.2.3 there are no material agreements existing to which the Authority is a party which prevent it from entering into this Agreement; and
- 15.2.4 all necessary actions to authorise the execution of and performance of its obligations under this Agreement have been taken before such execution.

#### Benefits of Warranties

- 15.3 Valneva agrees to use reasonable endeavours upon request to assign to the Authority the benefit of any warranty, guarantee or similar right which it has against any Third Party involved in the Manufacture of the Products in full or part, to the extent it is able to do so under the terms of its agreement with such Third Party.

#### Record Keeping

- 15.4 Valneva shall (and shall procure that its Affiliates shall) maintain all records and reports with respect to the Manufacture and supply of the Product (and in relation to the provision of any other services) under this Agreement as required by Applicable Laws and in any event for a minimum period of [\*\*\*] following the termination or expiry of this Agreement.

#### Product Recall

- 15.5 All reasonable costs of any recall or market withdrawal of the Product in the Territory, including reasonable costs and expenses incurred by or on behalf of Valneva and by the Authority and its Affiliates, shall be borne as follows:
- 15.5.1 where and to the extent that recall or market withdrawal results directly or indirectly from any Non-Compliance, those costs shall be borne by Valneva;
- 15.5.2 otherwise (including where recall or market withdrawal results from a breach of this Agreement by, or negligence on the part of, the Authority and/or any of its Affiliates or any of their respective Personnel) those costs shall be borne by the Authority.

15.6 Should any recall require to be undertaken, where it is reasonably practicable to do so and in circumstances where the recall has not been required by a Regulatory Authority, Valneva shall consult with the Authority in advance of such recall as to the reasons for it, and as to the most efficient method of executing the recall and Valneva shall use Commercially Reasonable Efforts to minimise the impact on the Authority of the recall.

16. **[\*\*\*], FUTURE PREPAREDNESS AND ACCESS TO FACILITIES**

16.1 If the Product is not Delivered in accordance with the Delivery Schedule and the terms of this Agreement or this Agreement is terminated before expiry in accordance with its terms, the Parties acknowledge and agree that the Authority shall, where and to the extent and in the manner specifically provided for under this Agreement, be entitled to compensation for the payments of the Price made pursuant to clause 13, Government [\*\*\*] Payments and [\*\*\*] by way of [\*\*\*] for [\*\*\*] and [\*\*\*] and pursuant to the remaining provisions of this clause 16. The Parties shall discuss in good faith the manner in which such compensation will be delivered.

16.2 Through the JSC, the Parties shall discuss in [\*\*\*] and [\*\*\*] (to the extent [\*\*\*] pursuant to [\*\*\*] of the [\*\*\*] made pursuant to clause 13 and the Government [\*\*\*] Payments) and the [\*\*\*] and [\*\*\*] in the [\*\*\*] of (i) [\*\*\*] for the [\*\*\*] of the Authority in respect of [\*\*\*] of the Product, [\*\*\*] and [\*\*\*] which in each case [\*\*\*] using [\*\*\*] and/or [\*\*\*] including in a circumstance in which the [\*\*\*] to [\*\*\*], and (ii) [\*\*\*] to the [\*\*\*] if there [\*\*\*] (whether or not [\*\*\*] to [\*\*\*]) and such [\*\*\*] shall be [\*\*\*] and [\*\*\*] the [\*\*\*] to such [\*\*\*].

16.3 [\*\*\*].

17. **ANTI-BRIBERY**

17.1 Valneva represents and warrants, on behalf of itself and its Affiliates, and, to the best of its knowledge, its and their respective Personnel, if any, directly and effectively involved, in the performance of this Agreement (together with Valneva, the “**Valneva Representatives**”) that:

17.1.1 it and the Valneva Representatives have not committed (directly or indirectly) any offence under the Bribery Act 2010 or done any of the following (“**Prohibited Acts**”):

- (a) offered, given or agreed to give any officer or employee of the Authority any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with the Authority or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the Authority; or
- (b) in connection with this Agreement paid or agreed to pay any commission other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the Authority; and

- 17.1.2 it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010; and
  - 17.1.3 the Valneva Representatives have not knowingly taken any action that will, or would reasonably be expected to, cause the Authority or its Affiliates to be in violation of any such laws.
- 17.2 If Valneva or Valneva Representatives (or anyone acting on its or their behalf) has done or does any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 with or without the knowledge of Valneva in relation to this Agreement:
- 17.2.1 Valneva shall be deemed to have committed a material breach of this Agreement and the Authority shall be entitled to terminate this Agreement in accordance with clause 25.4; and
  - 17.2.2 any termination under clause 17.2 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority.

## 18. **PRODUCT SECURITY**

- 18.1 The Authority shall be responsible for destruction of all Conforming Product in its possession for which the shelf life has expired or, at Valneva's request and at Valneva's cost, shall return the same to Valneva. Valneva shall be responsible for destruction of all Products that are Non-Compliant. In complying with its respective destruction obligations, the applicable Party shall undertake such destruction within mutually acceptable timelines, and prior to the destruction the applicable Party possessing the applicable Product shall hold the same securely pending destruction. Each Party shall keep a record of any destruction it undertakes and shall promptly issue certificates of destruction to the other Party upon request. Such records shall be kept for a period of at least [\*\*\*].
- 18.2 The Authority shall comply with all Applicable Laws relating to the traceability of pharmaceutical products applicable to the Products Delivered pursuant to this Agreement.
- 18.3 The Authority warrants and undertakes that it will not alter or modify any Product in any way (including Labelling and packaging but excluding any transportation packaging) after Delivery to the Delivery Locations.
- 18.4 After Delivery, all Products shall be: (i) stored securely by the Authority (or its Authorised Agents); and (ii) delivered, shipped and distributed by the Authority (or its Authorised Agents) in a secure manner appropriate to the transportation route and destination, in each case (i) and (ii) to guard against and deter theft, diversion, tampering or substitution (with, for example, counterfeits).

## 19. **INTELLECTUAL PROPERTY**

- 19.1 Neither Party will gain any rights of ownership to or use of any property or Intellectual Property Rights owned by the other (whether by virtue of this Agreement, by implication or otherwise).

- 19.2 Valneva represents and warrants as at the date of this Agreement that it owns all Intellectual Property Rights in the Product or it is licensed by the relevant owners to, and has the right to use the cell line used for, the Manufacture of the Product.
- 19.3 Valneva shall procure the necessary commercialisation licences required in respect of the virus strain and the Adjuvant used with the cell line for Manufacture of the Product which it anticipates it will secure by [\*\*\*].
- 19.4 Where the Development of the Product includes use of [\*\*\*], Valneva shall procure all necessary licences and supply agreements from the Adjuvant provider.
- 19.5 Valneva shall use Commercially Reasonable Efforts to procure licences to any other Third Party rights in order to Manufacture supply and distribute the Product in the Territory if and as necessary.
- 19.6 Valneva warrants to the Authority that any receipt, keeping, sale and use of the Product by the Authority, Authorised Agent or any Administering Entity or any Devolved Administration in accordance with this Agreement shall not infringe any Intellectual Property Rights of any Third Party.
- 19.7 Valneva shall indemnify and hold harmless the Authority any Authorised Agent, and Administering Entity against all claims, liabilities, losses, damages, costs (including reasonable legal costs) and expenses incurred in connection with any claim by any Third Party that its Intellectual Property Rights in the Product have been infringed as a result of the Manufacture or supply of the Product under this Agreement or the keeping, sale, or use of the Product where such keeping, sale and use of the Product has been undertaken in accordance with the terms of this Agreement.
- 19.8 Promptly following the Authority, any Authorised Agent or Administering Entity (the “[\*\*\*] Indemnitee”) receiving written notice of any matter which may result in it making a claim under the indemnity against Valneva (the “[\*\*\*] Indemnifying Party”) in clause 19.7, the [\*\*\*] Indemnitee shall:
- 19.8.1 give the [\*\*\*] Indemnifying Party notice of such matter [\*\*\*] on becoming aware of it;
- 19.8.2 not at any time admit liability or otherwise settle or compromise, or attempt to settle or compromise, the matter (or any aspect of it) except on the IP Indemnifying Party’s [\*\*\*];
- 19.8.3 give the [\*\*\*] Indemnifying Party sole conduct of the defence, negotiation or settlement of any such matter [\*\*\*];
- 19.8.4 act in accordance with the [\*\*\*] Indemnifying Party’s [\*\*\*] instructions, and give the IP Indemnifying Party such assistance as it may [\*\*\*] require in the conduct of any such defence, negotiation or settlement; and
- 19.8.5 take all [\*\*\*] steps to [\*\*\*] as a result of such matter.



20. **CONFIDENTIALITY**

- 20.1 Each Party shall treat the Confidential Information of the other Party as strictly confidential and not disclose it to any Third Party for any purpose whatsoever without obtaining the prior written consent of the other Party and not make use of the Confidential Information of the other Party or any part thereof other than as permitted under this Agreement, in each case other than to conduct its activities under this Agreement and as expressly permitted under this clause 20. Each Party agrees to treat such Confidential Information with at least the same care and in the same manner as its own secret and valuable information.
- 20.2 Valneva may disclose all or any part of the Confidential Information to its Affiliates, and to its and its Affiliates' respective Personnel and suppliers ("**Representatives**") as necessary to enable Valneva's performance under this Agreement, provided, however, that it ensures that such Representatives comply with the provisions of this clause 20. The Authority may disclose all or any part of the Confidential Information to Authorised Agents, Central Government Bodies and the Devolved Administrations ("**Representatives**") as necessary to enable the Authority's performance under this Agreement, provided, however, that it ensures that such Representatives comply with the provisions of this clause 20.
- 20.3 The confidentiality obligations and use restrictions set forth in clause 20.1 shall not apply to:
- 20.3.1 information that is or becomes generally available to the public (other than as a result of its disclosure by the receiving Party in breach of this clause 20);
- 20.3.2 information that was available to the receiving Party or its Representatives on a non-confidential basis before disclosure by the disclosing Party;
- 20.3.3 information that was, is or becomes available to the receiving Party or its Representatives on a non-confidential basis from a Third Party who, to the receiving Party's or the relevant Representative's knowledge, is not bound by a confidentiality agreement with the disclosing Party or otherwise prohibited from disclosing the information to the receiving Party or the Representative;
- 20.3.4 information that is developed by or for the receiving Party or its Representatives independently of the information disclosed by the disclosing Party; or
- 20.3.5 the disclosure of which is required to ensure the compliance of the Authority with any law including, but not limited to, the Freedom of Information Act 2000 (c.36) ("**FOIA**"), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities' Functions or on the Management of Records ("**Codes of Practice**") or the Environmental Information Regulations 2004 (SI 2004/3391) ("**Environmental Regulations**"), provided, however, that the Authority has provided reasonable advance notice of the impending disclosure to Valneva and provided further that it shall only disclose the Confidential Information to the extent strictly necessary.
- 20.4 Valneva agrees that:
- 20.4.1 without prejudice to the generality of clause 20.3.5, the provisions of this clause 20 are subject to the respective obligations and commitments of the Authority

and any Authorised Agent, Central Government Body, Administering Entity and Devolved Administration (as the case may be) under the FOIA, the Codes of Practice and the Environmental Regulations;

- 20.4.2 the decision on whether any exemption applies to a request for disclosure of recorded information is a decision solely for the Authority or an Authorised Agent, Central Government Body, Administering Entity or Devolved Administration (as the case may be); and
  - 20.4.3 where the Authority or an Administering Entity or Devolved Administration is managing a request as referred to in clause 20.4.2, Valneva shall co-operate with the Authority and any Authorised Agent, Central Government Body, Administering Entity or Devolved Administration making the request and shall respond within [\*\*\*] of any request by it for assistance in determining how to respond to a request for disclosure.
- 20.5 Valneva shall:
- 20.5.1 transfer any request for information, as defined under section 8 of the FOIA and/or the Environmental Regulations, to the Authority or an Authorised Agent, Central Government Body, Administering Entity or Devolved Administration as soon as practicable after receipt and in any event within [\*\*\*] of receiving a request for information;
  - 20.5.2 provide the Authority or an Authorised Agent, Central Government Body, Administering Entity or Devolved Administration with a copy of all relevant information in its possession that the Authority or an Authorised Agent, Central Government Body, Administering Entity or Devolved Administration requires within [\*\*\*] (or such other period as the Authority or an Authorised Agent, Central Government Body, Administering Entity or Devolved Administration may specify) of the Authority or an Authorised Agent, Central Government Body, Administering Entity or Devolved Administration requesting that information; and
  - 20.5.3 provide all reasonable assistance as reasonably requested by the Authority or an Authorised Agent, Central Government Body, Administering Entity or Devolved Administration to enable the Authority or an Authorised Agent, Central Government Body, Administering Entity or Devolved Administration to respond to a request for information within the time for compliance set out in section 10 of the FOIA.
- 20.6 Subject to clause 20.5 above, Valneva hereby gives consent for the Authority to publish this Agreement in its entirety (but with any information which is exempt from disclosure in accordance with the provisions of the FOIA and or the Environmental Information Regulations redacted), including from time to time agreed changes to this Agreement, to the general public.
- 20.7 The Authority may, at its sole discretion, redact information from this Agreement prior to publishing for one or more of the following reasons:
- 20.7.1 national security;

- 20.7.2 Personal Data;
  - 20.7.3 confidential information protected by Intellectual Property Rights;
  - 20.7.4 Third Party confidential information;
  - 20.7.5 IT security; or
  - 20.7.6 prevention of fraud.
- 20.8 The Authority must consult with Valneva to inform its decision regarding any exemptions and/or redactions prior to disclosing information but the Authority shall have the final decision. Any submissions made by Valneva regarding exemptions and/or redactions shall be made promptly by Valneva and considered in good faith by the Authority and if, notwithstanding those submissions, the Authority makes a decision to disclose the relevant information, the Authority will notify Valneva in writing of such decision as soon as is reasonably practicable prior to the date of intended disclosure.
- 20.9 Valneva shall assist and cooperate with the Authority to enable the Authority to publish this Agreement. The Authority will follow its own internal policies together with any applicable guidelines, including any published by the Treasury, the Cabinet Office or the Information Commissioner.
- 20.10 The Authority or an Authorised Agent, Central Government Body, Administering Entity or Devolved Administration will (to the extent legally permissible) consult Valneva in relation to any request for disclosure of Valneva's Confidential Information in accordance with all applicable guidance.
- 20.11 Each Party may disclose Confidential Information of the other Party if and to the extent that such disclosure is:
- 20.11.1 required by Applicable Laws, such as filing with securities regulators, or by an order of a Governmental Authority; provided that the receiving Party (where it is legally permitted to do so) shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to seek a protective order or other form of confidential treatment for the information, or obtain assurances that the information be used only for the purposes for which the order was issued, and the receiving Party shall thereafter disclose only that portion of the information required to be disclosed in order to comply;
  - 20.11.2 made by Valneva to a Regulatory Authority as reasonably necessary for the purposes of any filing, application or request for any marketing authorisation, licence or other Regulatory Approval made by or on behalf of Valneva or its Affiliates in respect of the Product;
  - 20.11.3 made by or on behalf of the receiving Party to (i) a potential acquirer, in each case as may be necessary in connection with their evaluation of a potential transaction but provided that (x) VLA shall procure that such potential acquirer first enters into a non-disclosure agreement with the Authority (acting reasonably and without undue delay), and (y) Valneva shall not provide the Authority's Confidential Information to such potential acquirer if the Authority has a

reasonably held concern, that on objective grounds, it would be inappropriate for such person to receive the Authority's Confidential Information; or (ii) legal, financial or other professional advisors, in each case for the purposes of advising on this Agreement and/or on the transactions contemplated hereby and thereby; provided however that, in each case, such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information and may only use such information for the purpose of assessing such transaction or providing such advice (as the case may be); or

20.11.4 for the purposes of any legal proceedings brought pursuant to clause 35.10.2;

provided that the Party making disclosures to a Third Party pursuant to clause 20.11.3 or clause 20.11.4 shall ensure that each Third Party recipient is bound by obligations of confidentiality no less restrictive than those contained in this Agreement and shall be liable to the other Party for any breach of such confidentiality obligations by the relevant recipient.

20.12 Nothing in this clause 20 shall prevent the Authority from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by Applicable Law. Nothing in this Agreement shall prevent the Authority from disclosing Confidential Information:

20.12.1 to any contracting authority as defined in Regulation 2 of the Public Contracts Regulations 2015 ("**Contracting Authority**"). All Contracting Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a Third Party which is not part of any Contracting Authority;

20.12.2 to any consultant, contractor or other person engaged by the Authority or any person conducting an Office of Government Commerce gateway review;

20.12.3 for the purpose of the examination and certification of the Authority's accounts; or

20.12.4 for any examination pursuant to Section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources.

20.13 The Authority may disclose the Confidential Information of Valneva:

20.13.1 on a confidential basis to any Central Government Body for any proper purpose of the Authority or of the relevant Central Government Body;

20.13.2 if required, to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirement;

20.13.3 to the extent the Authority (acting reasonably) deems disclosure necessary in the course of carrying out its public functions provided that the Authority shall take into account the reasonable concerns of Valneva in connection with any proposed disclosure and shall not disclose any trade secrets of Valneva;

- 20.13.4 on a confidential basis for the purpose of the exercise of its rights under this Supply Agreement, including the audit rights pursuant to clause 31; or
- 20.13.5 on a confidential basis to a proposed successor body in connection with any assignment, novation or disposal of any of its rights, obligations or liabilities under this Agreement,
- and for the purposes of the foregoing, references to disclosure on a confidential basis shall mean disclosure subject to a confidentiality agreement or arrangement containing terms no less stringent than those placed on the Authority under this clause 20.
- 20.14 The Authority and Valneva agree not to issue any press releases or public announcements concerning this Agreement or its terms without the prior written consent of the other Party to the form, timing and content of any such release or announcement, except as required by Applicable Laws, including disclosure required by any securities exchange.
- 20.15 Subject to clause 20.16, on expiry or termination of this Agreement or at any time at the disclosing Party's request, the receiving Party shall return to the disclosing Party all copies containing Confidential Information of the disclosing Party or, at the disclosing Party's option, destroy all copies of such Confidential Information. The return or destruction of the Confidential Information of the disclosing Party will not affect the receiving Party's obligation to observe the confidentiality and non-use restrictions in respect of that Confidential Information set out in this Agreement.
- 20.16 Each Party may keep one (1) copy of Confidential Information for evidence purposes at a secure place subject to the confidentiality and non-use obligations provided in this clause 20. The aforementioned return and destruction obligation shall not apply to electronic copies of Confidential Information which are rightfully contained in computers, word processors, communication systems and system-backup media (collectively "**IT Media**") which do not need to be destroyed or returned, provided that such IT Media are: (i) overwritten in the ordinary course of their reuse; or (ii) at all times maintained in confidence and not readily accessible and the receiving Party shall treat such copies as confidential in accordance with this clause 20.
- 20.17 This clause 20 shall remain in force without limit in time in respect of Confidential Information which comprises Personal Data or which relates to a patient, his or her treatment and/or medical records. Save as aforesaid, the obligations in this clause 20 shall last for the Term and for a period of [\*\*\*] thereafter.

## 21. PRODUCT LIABILITIES

21.1 For the purposes of this clause:

- 21.1.1 "**Product Liabilities**" means Losses paid to Third Parties [\*\*\*], in each case, pursuant to any Third Party claim involving actual or alleged [\*\*\*] caused by use of any [\*\*\*] pursuant to this Agreement.

- 21.1.2 “[\*\*\*] **Product Liabilities**” means Product Liabilities arising where there has been [\*\*\*] which has been [\*\*\*] or to the extent that [\*\*\*] have not taken reasonable steps to [\*\*\*].
- 21.1.3 “[\*\*\*] **Product Liabilities**” means Product Liabilities to the extent they arise from or caused by [\*\*\*] but excludes any such liability which is an [\*\*\*] Product Liability.
- 21.1.4 “[\*\*\*] **Product Liabilities**” means all Product Liabilities other than [\*\*\*] Product Liabilities and includes any and all [\*\*\*] Product Liabilities.
- 21.2 Valneva shall be responsible for, and shall indemnify and keep indemnified the Authority and its Affiliates and Health Service Bodies against, all [\*\*\*] Product Liabilities.
- 21.3 The Authority shall be responsible for, and shall indemnify and keep indemnified Valneva and its Affiliates against, all [\*\*\*] Product Liabilities other than:
- 21.3.1 any [\*\*\*] Product Liabilities arising from or caused by a [\*\*\*], or the [\*\*\*] of, Valneva or its Affiliates;
- 21.3.2 if, and to the extent that, Valneva secures insurance as agreed with the Authority in accordance with clause 21.4 in respect of [\*\*\*] Product Liabilities and Valneva shall be responsible for and shall indemnify, and keep indemnified, the Authority, its Affiliates and Health Service Bodies in respect of Losses paid [\*\*\*] for [\*\*\*] Product Liabilities to the extent such Losses are covered by such insurance; and
- 21.3.3 [\*\*\*] of any [\*\*\*] Product Liability (other than [\*\*\*] Product Liabilities [\*\*\*]) which Valneva shall be responsible for and shall indemnify, and keep indemnified, the Authority, its Affiliates and Health Service Bodies in respect of provided that Valneva shall not be required to pay the Authority more than [\*\*\*] per annum and Valneva’s liability under this clause 21.3.3 shall be reduced by [\*\*\*].
- 21.4 Valneva shall use its Commercially Reasonable Efforts to identify the availability of insurance on commercially viable terms with respect to some or all [\*\*\*] Product Liabilities. If Valneva:
- 21.4.1 identifies any insurance with respect to [\*\*\*] Product Liabilities; and
- 21.4.2 having regard to terms and cost of such insurance, Valneva considers it would be in the [\*\*\*] of Valneva and the Authority for Valneva to enter into such insurance,
- the parties will discuss in good faith [\*\*\*] to this Agreement (including [\*\*\*] and [\*\*\*]) and if the outcome of such discussions agrees such changes Valneva will enter into such insurance.

## Exclusions

- 21.5 Valneva will not be liable under the indemnity in clause 21.2 where the liability arises as a result of:
- 21.5.1 the [\*\*\*] which (i) is [\*\*\*] and which the [\*\*\*] are made aware of prior to [\*\*\*]; or (ii) the [\*\*\*] of the Product; or
- 21.5.2 any [\*\*\*] which is caused by any act or omission of [\*\*\*], or by any damage or event occurring whilst [\*\*\*].

## Conduct of Claims

- 21.6 Promptly following a Party or its Affiliate (or in the case of the Authority a Health Service Body) (the “**Indemnitee**”) becoming aware of any matter which may result in making a claim under the indemnity against the other Party (the “**Indemnifying Party**”) in clause 21.2 or 21.3, the Indemnitee shall:
- 21.6.1 give the Indemnifying Party notice of such matter [\*\*\*] on becoming aware of it;
- 21.6.2 not at any time admit liability or otherwise settle or compromise, or attempt to settle or compromise, the matter (or any aspect of it) except on the Indemnifying Party’s [\*\*\*];
- 21.6.3 give the Indemnifying Party sole conduct of the defence, negotiation or settlement of any such matter [\*\*\*];
- 21.6.4 act in accordance with the Indemnifying Party’s reasonable instructions, and give the Indemnifying Party such assistance as it may reasonably require in the conduct of any such defence, negotiation or settlement; and
- 21.6.5 take all reasonable steps to [\*\*\*] as a result of such matter.

## 22. **LIABILITY**

- 22.1 Except to the extent set out expressly in this Agreement, all conditions, warranties or other terms which might have effect between the Parties or be implied or incorporated into this Agreement (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by Applicable Laws. Without prejudice to the general nature of the previous sentence, unless this Agreement specifically states otherwise, neither Party makes any representations or warranties with respect to the Product, including any warranties as to non-infringement or fitness for a particular purpose.
- 22.2 In no circumstances shall either Party be liable to the other Party, whether arising in [\*\*\*] or otherwise, for:
- 22.2.1 any [\*\*\*]; or
- 22.2.2 any [\*\*\*] (in each case whether [\*\*\*]).
- 22.3 Nothing in this Agreement excludes or limits the liability of either Party for:
- 22.3.1 [\*\*\*] caused by [\*\*\*];

- 22.3.2 [\*\*\*] or [\*\*\*];
- 22.3.3 [\*\*\*];
- 22.3.4 in the case of [\*\*\*], failure to [\*\*\*] or any other [\*\*\*] under this Agreement; or
- 22.3.5 any other matter to the extent that [\*\*\*].
- 22.4 Save in respect of liabilities pursuant to the indemnities in [\*\*\*], Valneva's [\*\*\*] arising from or in connection with this Agreement and the supply of Products pursuant to this Agreement will not [\*\*\*]:
  - 22.4.1 in the case of a failure to [\*\*\*] in accordance with this Agreement or a [\*\*\*] this Agreement which otherwise is [\*\*\*], the [\*\*\*]; and
  - 22.4.2 otherwise, a [\*\*\*] as at the date of [\*\*\*] of such [\*\*\*] to the [\*\*\*] of [\*\*\*] in respect of liabilities arising up to [\*\*\*] the [\*\*\*] of [\*\*\*] in respect of liabilities arising in [\*\*\*] the [\*\*\*] subject to this [\*\*\*] discharged prior to the [\*\*\*] of such liability provided that the [\*\*\*] shall in no event [\*\*\*].
- 22.5 Neither Party shall be entitled under any provision of this Agreement to recover damages, or obtain payment, reimbursement, restitution or indemnity [\*\*\*] in respect of the [\*\*\*].
- 22.6 Neither Party shall be liable to the other Party for any claim under this Agreement to the extent that the Party bringing such claim (or any of its Affiliates) [\*\*\*].
- 22.7 [\*\*\*]

## 23. **INSURANCE**

Valneva shall take out and maintain with a reputable commercial insurer such types and amounts of liability insurance to cover liabilities related to its activities under this Agreement for product liability claims, and for such other losses as are normal and customary in the pharmaceutical industry generally for Persons similarly situated, and shall upon request provide to the Authority evidence of its insurance coverage. Such policies shall include product liability insurance, clinical trial insurance, manufacturing insurance and general liability insurance, and shall remain in effect throughout the Territory and the Term and for a period of [\*\*\*] thereafter, each with a minimum limit of indemnity of [\*\*\*] per claim and per annum or such other sum as may be agreed between the Authority and Valneva in writing and subject to other standard exclusions, limitations and terms.

## 24. **FORCE MAJEURE**

- 24.1 If a Party is prevented from or delayed in performing any of its obligations under the Agreement by a Force Majeure then:
  - 24.1.1 the relevant obligations under this Agreement shall be suspended for as long as the Force Majeure continues and the affected Party shall not be in breach of this Agreement or otherwise liable for any such failure or delay in the performance of such obligations;



- 24.1.2 as soon as reasonably practicable after the start of the Force Majeure, the affected Party shall notify the other Party of the nature of the Force Majeure and the likely effects of the Force Majeure on its ability to perform its obligations under this Agreement; and
- 24.1.3 as soon as reasonably practicable after the end of the Force Majeure, the affected shall notify the other Party that the Force Majeure has ended, and shall resume performance of its obligations under this Agreement.

## 25. DURATION AND TERMINATION

- 25.1 This Agreement commences and takes effect on the Effective Date and shall continue until the date on which quantities of Conforming Product equal to the volumes in the Orders have been Delivered in full to Authority (the “**Initial Term**”), unless and to the extent this Agreement is (i) terminated earlier by a Party or the Parties in accordance with the provisions of this clause 25; or (ii) extended by agreement between the Parties (the “**Term**”).
- 25.2 The Authority shall be entitled to terminate this Agreement upon [\*\*\*] written notice to Valneva if the Product presents material safety issues, or significantly lacks efficacy [\*\*\*] which on a reasonable and objective basis does not readily support the continuation of the Development of the Product for use within the Field, or the Product or is otherwise discontinued or withdrawn from the market in any country for safety, quality or regulatory reasons provided that the Authority shall have entered into good faith discussions with Valneva during the notice period regarding such issues and shall have taken reasonable account of any relevant information provided by Valneva to it before the end of the notice period.
- 25.3 A Party who has been served notice of a Force Majeure event pursuant to clause 24 by the other Party may service written notice to terminate this Agreement if the Force Majeure event has led to the suspension of the affected Party’s obligations for [\*\*\*] or more.
- 25.4 Either Party (the “**Terminating Party**”) shall be entitled to terminate this Agreement before the expiry of the Term in its sole discretion and upon written notice to that effect to the other Party, for material breach of this Agreement, by the other Party (the “**Breaching Party**”), if:
- 25.4.1 subject to clause 25.4.2, the Breaching Party fails to comply with any of the material obligations under this Agreement, the consequences of which are material in the context of this Agreement taken as a whole, and fails to remedy the violation or breach within [\*\*\*] (in each case, the “**Cure Period**”) of being notified of such breach in writing by the Terminating Party. In such event, the right of the Terminating Party to claim damages for breach of contract shall remain unaffected;
- 25.4.2 the Breaching Party may during the Cure Period commence legal proceedings to challenge the validity of the notice served by the Terminating Party alleging that the Breaching Party has committed a material breach of this Agreement, in which case, termination shall not occur until the court makes a decision (which decision is not capable of appeal or which is not appealed within the time limited allowed for appeal) that the event(s) specified in the Terminating Party’s written notice does entitle the Terminating Party to terminate this Agreement.

- 25.5 It is expressly acknowledged that neither Party shall be in breach of this Agreement to the extent its failure to perform, or its delay in performing, any obligation under this Agreement is as a result of the other Party's failure to perform, or delay in performing the obligations set out in this Agreement upon which the first Party's performance is dependent.
- 25.6 The Authority shall be entitled to terminate this Agreement before the expiry of the Term, [\*\*\*] written notice to that effect to Valneva, provided however, that:
- 25.6.1 the Authority shall upon termination, pay the balance of the following amounts:
- (a) any Adjuvant Commitment existing prior to the date of notice of termination; and/or
  - (b) any amounts in respect of Required Commitments and which, at the time of notice, are Irrevocably Committed and the provisions of clause 7.8 shall continue to apply; and/or
  - (c) any amounts in respect of [\*\*\*] which, at the time of notice, are Irrevocably Committed, it being acknowledged that upon commencement of the [\*\*\*] or the [\*\*\*], the [\*\*\*] associated with [\*\*\*] of that particular [\*\*\*] will be Irrevocably Committed, but it being further acknowledged that Valneva will use Commercially Reasonable Efforts to mitigate and minimise any such costs upon early termination of this Agreement including by way of early termination of that [\*\*\*]; and/or
- 25.6.2 Valneva shall not be obliged to refund or repay any Paid Amount;
- 25.6.3 clause 7.11 shall apply and the Net Funding shall be the relevant specified amount; and
- 25.6.4 Valneva shall use Commercially Reasonable Efforts to mitigate and minimise any such costs payable pursuant to clause 25.6.1.
- 25.7 The Authority shall be entitled to terminate this Agreement before the expiry of the Term upon written notice to that effect to Valneva if there is any Loss of Supply. Upon termination under this clause, the provisions of clause 9.8 shall apply and clause 26.1.2 shall not apply.
- 25.8 The Authority shall be entitled to terminate this Agreement in accordance with its rights under:
- 25.8.1 clause 4.17; or
  - 25.8.2 clause 13.7.4 whereupon the provisions of clause 13.7.4(b) shall continue to apply.

- 25.9 The Authority shall be entitled to terminate this Agreement before the expiry of the Term in its sole discretion and upon written notice to that effect to Valneva, as detailed below and to the extent permitted by Applicable Laws, if:
- 25.9.1 any resolution is passed, or application made, in relation to Valneva for a moratorium on the payment of its debts, or for its dissolution, liquidation, winding-up or administration; or
  - 25.9.2 a receiver, liquidator, administrator or administrative receiver (or equivalent officer) is appointed over Valneva or its undertaking or all or a substantial part of its assets; or
  - 25.9.3 Valneva suffers any event in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events described in this clause 25.9; or
  - 25.9.4 Valneva ceases or threatens to cease to carry on business.
- 25.10 The Authority shall be entitled to terminate this Agreement before the expiry of the Term in its sole discretion and upon written notice:
- 25.10.1 if Valneva undergoes a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (other than for an intra-group change of control) without the prior written consent of the Authority and the Authority shall be entitled to withhold such consent if, in the reasonable opinion of the Authority, the proposed change of control will have a material impact on the performance of this Agreement or the reputation of the Authority;
  - 25.10.2 in accordance with its rights under clause 17.2.1, 31.8 or 31.10;
  - 25.10.3 if Valneva purports to assign, sub-contract, novate, create a trust in or otherwise transfer or dispose of this Agreement in breach of its terms, including those at clauses 35.5 and 35.6;
  - 25.10.4 Valneva commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by clause 32 or Valneva fails to provide details of proposed mitigating factors as required by clause 32 that in the reasonable opinion of the Authority are acceptable; or
  - 25.10.5 there has been a material failure having material consequences, by Valneva and/or one of its Affiliates and/or Subcontractors to comply with material legal obligations applicable in the Territory in the fields of environmental, social or labour law. Where the failure to comply with legal obligations in the fields of environmental, social or labour law is a failure by one of Valneva's Subcontractors, the Authority may request the replacement of such Subcontractor and Valneva shall comply with such request as an alternative to the Authority terminating this Agreement under this clause 25.10.5

## 26. CONSEQUENCES OF TERMINATION

26.1 Upon expiry or termination of this Agreement for any reason:

26.1.1 the Authority shall pay the Price and any other sums which in each case are owed to Valneva pursuant to this Agreement at the date of expiry or termination within [\*\*\*] of the date of invoice for the same save to the extent any sums due or payable are applicable to (i) any act or omission by Valneva or its Affiliates that amounts to a breach of this Agreement; or (ii) any payment of the [\*\*\*] where notice to terminate pursuant to clause 25.2 has been served within [\*\*\*] of such invoice; or (iii) any Orders to the extent the same have been cancelled or reduced as a consequence of a Loss of Supply and for which Product has not been Delivered pursuant to this Agreement;

26.1.2 other than for a termination pursuant to clause 25.4, 25.6, 25.9 or 25.10, save where otherwise specified, upon such Termination, the Authority shall be required to pay to Valneva, any amounts Irrevocably Committed by Valneva in respect of Required Commitments or [\*\*\*] save to the extent any sums are the subject of any act or omission by Valneva or its Affiliates that amounts to a breach of this Agreement;

26.1.3 each Party shall use Commercially Reasonable Efforts to mitigate both (a) the damages (if any) that would otherwise be recoverable from the other pursuant to this Agreement, and (b) any costs, fees, expenses or losses that may be incurred by a Party, or for which a Party may be responsible, under this Agreement, by taking appropriate and reasonable actions to reduce or limit the amount of such damages, costs, fees, expenses or losses;

26.1.4 the provisions of clause 7.11 shall apply and the Net Funding shall be the relevant specified amount in such clause;

26.1.5 any provision of this Agreement which expressly or by implication is intended to come into or continue in force, including clauses 1, 7.8, 7.11, 7.12, 9.8, 12.2, 14 (to the extent that payments to Valneva or the Authority are due or still owing), 15, 16, 18.1, 20, 21, 22, 23, 26, and 31, shall remain in full force and effect.

26.2 Expiry or termination of this Agreement for any reason shall be without prejudice to either Party's other rights and remedies or to any accrued rights and liabilities as the date of such expiry or termination which shall survive such termination or expiry.

26.3 For the avoidance of doubt, expiry or termination of this Agreement shall terminate any Order placed under or pursuant to this Agreement which has not been, or to the extent it has not been, fulfilled at the date of expiry or termination.

## 27. DATA PROTECTION

27.1 Each Party shall comply with Data Protection Laws in respect of any Personal Data provided to it by the other Party under, or in connection with the performance of its obligations under, this Agreement or in the case of the Authority, related to the use of the Product by the Authority or any person to whom it is supplied pursuant to this Agreement. In particular, in respect of such Personal Data, each Party agrees to comply with the obligations placed on it by the Principle (f) (the "**Integrity Principle**") set out in the Data Protection Laws.

27.2 Both Parties agree to use all reasonable efforts to assist each other to comply with Data Protection Laws, including in relation to subject access requests.

28. **INTERNATIONAL ACCESS**

28.1 Valneva shall discuss with the Authority and other national governments with a view to ensuring that in addition to fulfilling the Authority's [\*\*\*], the Product may also be made available to developing countries around the world to help control the pandemic in the Field. For the avoidance of doubt, this provision does not restrict in any way Valneva's right to contract with other national governments or any other Third Party, nor does it restrict Valneva from fulfilling its obligations under this Agreement or any other agreement.

29. **GUARANTEE**

29.1 Parent shall procure the performance of the obligations of Valneva hereunder and shall remedy any non-performance or breach thereof. Accordingly, as a condition to this Agreement, Parent shall enter into the guarantee in the form set out in Schedule 12.

30. **INDEPENDENT CONTRACTORS**

Valneva is acting as an independent contractor under this Agreement. Nothing in this Agreement or any circumstances associated with it or its performance give rise to any relationship of agency, partnership or employer and employee between the Authority and Valneva or between the Authority and any Valneva Representative, nor authorise either Party to make or enter into any commitments for or on behalf of the other Party.

31. **RIGHT OF AUDIT, CONFLICTS OF INTEREST AND PREVENTION OF FRAUD**

31.1 Valneva shall keep secure and maintain for the Term of this Agreement and [\*\*\*] (or from the date of the last delivery, if later), or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Agreement.

31.2 Valneva shall grant to the Authority or its authorised agents, such access to those records as they may reasonably require (i) in order to check Valneva's compliance with this Agreement, and (ii) for the purposes of any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which the Authority has used its resources.

31.3 The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of Valneva and may require Valneva to provide such oral and/or written explanations as they consider necessary. This clause does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of Valneva under section 6(3)(d) and 6(5) of the National Audit Act 1983.

31.4 The Authority shall have the right, upon having reasonable grounds to suspect or believe that there has been a non-compliance, to audit Valneva's compliance with this Agreement. Valneva shall permit or procure permission for the Authority or its authorised representative during normal business hours having given advance notice of no less than [\*\*\*], access to any premises and facilities, books and records used in the performance of Valneva's obligations under this Agreement.

- 31.5 Should Valneva subcontract any of its Manufacturing obligations under this Agreement (including in respect of fill/finish obligations), Valneva will use Commercially Reasonable Efforts to ensure that the relevant subcontract permits the Authority to audit (including but not limited to a financial audit and a full manufacturing audit) and inspect such Affiliate or Third Party, provided that this requirement shall not apply to any subcontract entered into by Valneva prior to the date of this Agreement.
- 31.6 Valneva shall use Commercially Reasonable Efforts to procure permission for the Authority or its authorised representative during normal business hours no more than [\*\*\*] in any [\*\*\*] having given advance notice of no less than [\*\*\*], access to any premises and facilities, books and records used in the performance of Valneva's Manufacturing obligations under this Agreement, including any that are subcontracted to such Third Party. Valneva shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if reasonably requested to do so.
- 31.7 Valneva shall take appropriate steps to ensure that neither Valneva nor any staff is placed in a position where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of Valneva (save as they relate to the terms of this Agreement) and the duties owed to the Authority under the provisions of this Agreement. Valneva will disclose to the Authority full particulars of any such conflict of interest which may arise.
- 31.8 The Authority reserves the right to terminate this Agreement with immediate effect by giving notice in writing and/or to take such other steps it deems necessary where, in the reasonable opinion of the Authority, there is an actual conflict, between the pecuniary or personal interests of Valneva (save as they relate to the terms of this Agreement) and the duties owed to the Authority under the provisions of this Agreement. The actions of the Authority pursuant to this clause 31.7 shall not prejudice or affect any right of action or remedy which shall have accrued or shall thereafter accrue to the Authority.
- 31.9 Valneva shall take all reasonable steps to prevent Fraud by staff and Valneva in connection with the receipt of monies from the Authority. Valneva shall notify the Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.
- 31.10 If Valneva or its staff commits Fraud in relation to this or any other contract with the Crown (including the Authority) the Authority may terminate this Agreement.

## 32. TAX NON-COMPLIANCE

- 32.1 If, at any point during the Term of this Agreement, an Occasion of Tax Non- Compliance occurs, Valneva shall:
- 32.1.1 notify the Authority in writing of such fact within [\*\*\*] of its occurrence; and
- 32.1.2 promptly provide to the Authority:

- (a) details of the steps which Valneva is taking to address the Occasion of Tax Non-Compliance and to prevent the same from recurring, together with any mitigating factors that it considers relevant; and
- (b) such other information in relation to the Occasion of Tax Non- Compliance as the Authority may reasonably require.

### 33. ENVIRONMENTAL CONSIDERATIONS

- 33.1 In complying with its obligations under this Agreement, Valneva shall comply in all material respects with applicable environmental laws and regulations in force from time to time in relation to the Product. Without prejudice to the generality of the foregoing, Valneva shall:
- 33.1.1 comply with all reasonable stipulations of the Authority aimed at minimising the packaging in which the Product is supplied to the Authority under this Agreement;
  - 33.1.2 promptly provide such data as may reasonably be requested by the Authority from time to time regarding the weight and type of packaging according to material types used in relation to the Product supplied to the Authority under this Agreement;
  - 33.1.3 comply with all obligations imposed on it in relation to the Product supplied to the Authority under this Agreement by the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (SI 2007/871) (or any other equivalent legislation giving effect in any part of the European Economic Area to the Packaging and Packaging Waste Directive 94/62/EC as amended);
  - 33.1.4 without prejudice to Valneva's other obligations under this Agreement, label all units of the Product supplied to the Authority under this Agreement, and the packaging of those units, to highlight environmental and safety information as required by Applicable Laws.

### 34. EQUALITY, NON-DISCRIMINATION, HUMAN RIGHTS AND CONDUCT

- 34.1 Valneva shall not:
- 34.1.1 engage in any prohibited conduct as defined in part 2 chapter 2 of the Equality Act 2010 (c.15) (the "**Equality Act**") in relation to any protected characteristic (as defined in section 4 of the Equality Act) where this would contravene any provisions of the Equality Act, including part 3 (goods and services) and part 5 (employment); or
  - 34.1.2 do (or omit to do) anything else that would amount to a contravention of the Equality Act including part 8 (prohibited conduct: ancillary) and chapter 3 part 5 (equality of terms),
- in each case where Valneva is required under Applicable Laws to take, or not take, such action.

- 34.2 Valneva shall notify the Authority immediately of any investigation of or proceedings against Valneva under the Equality Act or any predecessor legislation and shall cooperate fully and promptly with any requests of the person or body conducting such investigation or proceedings, including allowing access to any documents or data required, attending any meetings and providing any information requested.
- 34.3 Other than in respect of Subcontracts entered into prior to the date of this Agreement, Valneva shall use Commercially Reasonable Efforts to impose on any Subcontractor obligations substantially similar to those imposed on Valneva by this clause 34 where that Subcontractor is subject to the requirements of the Equality Act.
- 34.4 In addition to its obligations under this clause 34 relating to Equality Act, Valneva shall ensure that it complies with all other applicable current employment legislation and, in particular, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 (SI 2000/1551), the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002, (SI 2002/2034), the National Minimum Wage Regulations 2015 (as amended by the National Minimum Wage (Amendment) Regulations 2016) and any equivalent legislation applicable in Scotland, Northern Ireland and/or Wales or any other relevant legislation relating to discrimination in the employment of employees
- 34.5 Valneva shall, and shall use reasonable endeavours to ensure that its employees or agents shall, at all times, act in a way which is compatible with the Convention rights within the meaning of Section 1 of the Human Rights Act 1998 (c.42).
- 34.6 Valneva shall (i) comply with all Applicable Law and Guidance to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify the Authority immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains.
- 34.7 Valneva shall use Commercially Reasonable Efforts to comply with the Supplier Code of Conduct within a reasonable period from the Commencement Date for the remaining duration of the Agreement. For the avoidance of doubt, if, notwithstanding Valneva's use of Commercially Reasonable Efforts Valneva is not at any time in full compliance with the Supplier Code of Conduct, Valneva shall not be considered in breach of this Agreement.

35. **MISCELLANEOUS**

35.1 Notices

35.1.1 All communications relating to this Agreement shall be in writing and delivered by hand or sent by post to the Party concerned at the relevant address set out in this clause 35.1 below (or such other address as may be notified from time to time in accordance with this clause 35.1 by the relevant Party to the other Party). Any communication shall take effect:

- (a) if hand delivered, upon being handed personally to the addressee (or, where the addressee is a corporation, any one of its directors or its secretary) or being left in a letter box or other appropriate place for the receipt of letters at the relevant Party's address as set out below;



- (b) if sent by first class registered post, at 10 a.m. on the second Business Day after posting or if overseas by international recorded post, at 10 a.m. on the fifth Business Day after posting.

No notice served by email shall be effective.

- 35.1.2 A notice sent by post (or the envelope containing it) shall not be deemed to be duly posted for the purposes of this clause 35.1 unless it is put into the post properly stamped or with all postal or other charges in respect of it otherwise prepaid.

**For Notices to the Authority:**

Secretary of State, Department for Business, Energy and Industrial Strategy  
1 Victoria St  
Westminster  
London SW1H 0ET

Attn: Director General of the UK Vaccine Taskforce

With a copy to : Permanent Secretary, Department for Business, Energy & Industrial Strategy at the above address.

**For Notices to Valneva:**

Valneva Austria GmbH  
Campus Vienna Biocenter 3  
1030 Vienna  
Austria

Attn: [\*\*\*]

With a copy to:

Valneva SE  
6 rue Alain Bombard  
44800 Saint Herblain  
France

Attn: [\*\*\*]

[\*\*\*]

35.2 Variation and Waiver

- 35.2.1 No amendment or variation of the terms of this Agreement shall be effective unless it is made or confirmed in a written document signed by both Parties to this Agreement.
- 35.2.2 Any waiver of any right, obligation or remedy under, or compliance with or breach of any provision of, this Agreement must be expressly stated in writing to be such a waiver, must specify the right, remedy, obligation, provision or breach to which it applies and must be signed by an authorised signatory of each of the Parties granting the waiver. If either Party waives any right, obligation or remedy

under, or compliance with or breach of any provision of this Agreement, it can still enforce that right, obligation or provision or claim that remedy subsequently and that waiver shall not be deemed to be a waiver of any subsequent breach of that or any other provision or of any other right, obligation or remedy.

- 35.2.3 The rights and remedies of either Party in respect of this Agreement shall not be diminished, waived or extinguished by the granting of any indulgence, forbearance or extension of time by either Party to the other nor by any failure to ascertain or exercise, or any delay in ascertaining or exercising, any such rights or remedies.
- 35.2.4 The discontinuance, abandonment or adverse determination of any proceedings taken by either Party to enforce any right or any provision of this Agreement shall not operate as a waiver of, or preclude any exercise or enforcement or (as the case may be) further or other exercise or enforcement by that Party of, that or any other right or provision.
- 35.2.5 All references in this clause 35.2 to any right or remedy shall include any power, right or remedy conferred by this Agreement on, or provided by law or otherwise available to, the relevant Party; and any right not being exercised shall include any partial exercise of that right and any circumstances in which the relevant Party does not insist on the strict performance of any provision of this Agreement.
- 35.2.6 The giving by either Party of any consent to any act which by the terms of this Agreement requires that consent shall not prejudice the right of that Party to withhold or give consent to the doing of any similar act.

### 35.3 Counterparts

- 35.3.1 This Agreement may be executed in any number of counterparts, and by the Parties on separate counterparts, but shall not be effective until each Party has executed at least one (1) counterpart. Each counterpart shall constitute an original of this Agreement, but all the counterparts shall together constitute the one agreement.
- 35.3.2 Delivery of a copy of this Agreement together with an executed signature page of a counterpart in Adobe™ Portable Document Format (PDF) sent by electronic mail shall take effect (subject to clause 35.11) as delivery of an executed counterpart of this Agreement. If this method is adopted, without prejudice to the validity of this Agreement, each Party shall provide the other with a hard copy original of that executed counterpart as soon as reasonably practicable thereafter.

### 35.4 Invalidity

Each provision of this Agreement is severable and distinct from the others. The Parties intend that each of those provisions shall be and remain valid and enforceable to the fullest extent permitted by Applicable Laws. If all or any part of any such provision is held to be or at any time becomes to any extent invalid, illegal or unenforceable for any reason under any enactment or rule of law, it shall to that extent be deemed not to form part of this Agreement but (except to that extent in the case of that provision) it and all

other provisions of this Agreement shall continue in full force and effect and their validity, legality and enforceability shall not be affected or impaired as a result, subject to the operation of this clause 35.4 not negating the commercial intent and purpose of the Parties under this Agreement.

### 35.5 Assignment

- 35.5.1 A Party may, but only with the other Party's prior written consent, assign or transfer, in whole or in part, this Agreement or any of its rights and obligations under this Agreement to one or more of its Affiliates.
- 35.5.2 Valneva will procure that, before any assignee subsequently ceases to be a member of Valneva's Group, the assignee shall assign back to Valneva for the purposes of this clause, so much of the benefit of this Agreement as has been assigned to it.
- 35.5.3 Valneva may, but only with the Authority's prior written consent, assign or transfer, in whole or in part, this Agreement or any of its rights and obligations under this Agreement to any Third Party, but otherwise may not assign this Agreement, in whole or part, to any Third Party.
- 35.5.4 Where this clause applies in accordance with clause 13.7.4(c):
- (a) the Authority may, with Valneva's consent (such consent not to be unreasonably withheld or delayed) assign in whole or in part its rights and obligations under this Agreement to one or more Third Parties and where the Authority assigns part of its rights and obligations the Authority shall be entitled to specify the extent to which each of the Authority and each assignee shall be entitled to the benefit of such rights and responsible for the burden of such obligations; and
  - (b) Valneva shall make Commercially Reasonable Efforts to support the Authority in any process whereby the Authority seeks to secure assignees of the whole or parts of its rights and obligations under this Agreement, including the provision to the Authority and potential assignees of reasonable diligence materials and access to management and technical experts for diligence purposes provided that in the case of each potential assignee such assignee has first executed a non-disclosure agreement in favour of Valneva on terms reasonably acceptable to Valneva.
- 35.5.5 Any permitted assignment or transfer by one Party shall be effective only if the relevant assignee confirms in writing to, and upon receipt by, the other Party that it shall fully adhere to all the provisions of this Agreement as if it were an original party to this Agreement.
- 35.5.6 This Agreement shall be binding on and inure for the benefit of the successors and permitted assignees of the Parties.

35.6 Sub-contracting

35.6.1 Valneva may, without the need for the Authority's consent but subject to clause 35.6.2, sub-contract or delegate its obligations or services to be provided under this Agreement to one or more of its Affiliates and/or to any Third Party consultant or contractor (a "Subcontractor").

35.6.2 Valneva shall at all times remain responsible and liable to the Authority for the acts or omissions of Valneva's Affiliates and Subcontractors to whom Valneva sub-contracts or delegates any of its obligations, as if those acts or omissions were of its own.

35.7 No Rights of Third Parties

Save as provided in this Agreement, including pursuant to clause 21, a person who is not a Party to this Agreement or an Affiliate of such Party shall not have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement. Notwithstanding any rights any Third Party may have by virtue of the foregoing, the Parties to this Agreement may vary, amend or terminate this Agreement without seeking the consent of any Third Party whose rights may be affected.

35.8 Costs

Each Party will be responsible for all costs incurred by it or on its behalf in connection with this Agreement.

35.9 Entire Agreement

This Agreement, and any agreement or document referred to in it, together with the schedules herein contains the entire agreement between the Parties with respect to the subject matter of this Agreement, and supersedes all previous agreements and understandings between the Parties with respect to that subject matter (including without limitation, the Confidentiality Agreement, Heads of Terms and Commitment Letter each of which is hereby terminated, save for those terms in each such agreement that expressly survive termination). Each Party acknowledges that, in entering into this Agreement and the agreements and documents referred to in it, it does not rely on any statement, representation, assurance or warranty (whether it was made negligently or innocently) of any person (whether a Party to this Agreement or not) which is not expressly set out in this Agreement or those documents (a "Representation"), and that it shall have no cause of action against the other Party arising out of any Representation except in respect of any fraudulent misrepresentation by the other Party.

35.10 Governing Law and Jurisdiction

35.10.1 This Agreement and any issues, disputes or claims arising out of or in connection with it (whether contractual or non-contractual in nature, including claims in tort or for breach of any statute or Applicable Law) shall be governed by and construed in accordance with English law.

35.10.2 If a dispute arises between the Parties in connection with or relating to this Agreement (a "Dispute"), either Party shall have the right to refer such Dispute to senior representatives [\*\*\*] for attempted resolution by good faith negotiations during a period of [\*\*\*]. Any final decision mutually agreed to by such senior officers in writing shall be conclusive and binding on the Parties.

35.10.3 Subject to clause 35.10.2, each Party irrevocably submits to the exclusive jurisdiction of the English courts to settle any dispute which may arise under or in connection with this Agreement or the legal relationships established by this Agreement.

35.11 Further Assurance

Each Party shall, with respect to its obligations, take such action or procure that such action is taken as is reasonable in order to fulfil its obligations and implement the terms of this Agreement or any transaction, matter or thing contemplated by this Agreement.

35.12 Delivery of Agreement

The Parties do not intend this Agreement to be delivered by, or to become legally binding on, any of them until the date of this Agreement is written at its head, notwithstanding that one or more of them may have executed this Agreement prior to that date being inserted.

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be executed in two counterparts by their respective duly authorised representatives as of the date set forth at the beginning of this Agreement.

SIGNED by [\*\*\*] ,)  
Authorised Signatory for and on behalf of )  
**VALNEVA S.E.** ) [\*\*\*]

SIGNED by [\*\*\*] ,)  
Authorised Signatory for and on behalf of )  
**VALNEVA AUSTRIA GMBH** ) [\*\*\*]

SIGNED by [\*\*\*] ,)  
Authorised Signatory for and on behalf of )  
**VALNEVA AUSTRIA GMBH** ) [\*\*\*]

SIGNED by [\*\*\*] ,)  
Authorised Signatory for and on behalf of )  
**THE SECRETARY OF STATE FOR** ) [\*\*\*]  
**BUSINESS, ENERGY AND**  
**INDUSTRIAL STRATEGY**

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**SCHEDULE 1**  
**CANDIDATE, PRODUCT AND SPECIFICATIONS**

[\*\*\*]

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**SCHEDULE 2  
FACILITIES**

[\*\*\*]



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**SCHEDULE 3**  
**KEY PERFORMANCE INDICATORS AND MEETING SCHEDULE**

[\*\*\*]

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**SCHEDULE 4  
DEVELOPMENT PLAN**

[\*\*\*]

---

**SCHEDULE 5  
FACILITY PLAN**

[\*\*\*]

---

**SCHEDULE 6**  
**MANUFACTURING PLAN**

[\*\*\*]

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**SCHEDULE 7  
DELIVERY SCHEDULE**

[\*\*\*]

**SCHEDULE 8**  
**DOCUMENTATION & INFORMATION TO ACCOMPANY DELIVERIES**

- Pack list and quantity of Doses
- Certificate of Conformance and Analysis (and where relevant, Certificate of Origin) Product description
- Batch details
- Expiry date
- Certification on storage and transport temperature control Storage and transport instructions
- Other information and notices required by the Marketing Authorisation and Applicable Laws.
- Quality Person contact details

Note: some of the information required above may be provided aggregated with other data in one document.

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**APPENDIX 1**

**INITIAL ORDER FORM**



**Department for  
Business, Energy  
& Industrial Strategy**

1 Victoria Street  
London SW1H 0ET

T +44 (0) 20 7215 5000  
E [www.beis.gov.uk/contact](http://www.beis.gov.uk/contact)

[www.beis.gov.uk](http://www.beis.gov.uk)

Valneva S.E.  
Valneva Austria GmbH (collectively “Valneva”)  
Campus Vienna Biocenter 3  
1030 Vienna  
Austria

### **Order**

#### **pursuant to the Supply Agreement dated 13th September 2020**

We refer to the Supply Agreement between Valneva S.E., Valneva Austria GmbH and The Secretary of State for Business, Energy and Industrial Strategy dated September 2020 (“Agreement”). Capitalised terms used in this Order have the meaning set forth in the Agreement.

The Authority hereby places an Order with Valneva as required by Clause 8.1 of the Agreement for thirty million (30m) Regimens of the Product to be Delivered pursuant to the terms of the Agreement. This Order is placed exclusively on the terms of the Agreement.

Yours faithfully

[\*\*\*]

**Authorised Signature**

**For and on behalf of the Department for Business Energy and Industrial Strategy**



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**[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.**

**DATED 17<sup>th</sup> DECEMBER 2020**

**VALNEVA SE**

**VALNEVA AUSTRIA GMBH**

**AND**

**THE SECRETARY OF STATE FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY**

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**FIRST AMENDMEMENT AGREEMENT TO THE  
SARS-COV2 VACCINE SUPPLY AGREEMENT**

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THIS AMENDMENT AGREEMENT (“*Amendment Agreement*”) is dated 17<sup>th</sup> December 2020 (“*Amendment Date*”) and made between:

- (1) VALNEVA S.E., a company registered in France (company number 422,497,560) whose registered address is at 6 rue Alain Bombard 44800 Saint Herblain, France (“*Parent*”); and
  - (2) VALNEVA AUSTRIA GMBH, a company registered in Austria (company number FN 389960 x /HG Wien) whose registered address is at Campus Vienna Biocenter 3, 1030 Vienna, Austria (“*Valneva*”); and
  - (3) THE SECRETARY OF STATE FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY, acting on behalf of the Crown, whose principal office is at 1 Victoria Street, London, SW1H 0ET (the “*Authority*”),
- (each a “*Party*”, and collectively the “*Parties*”).

## INTRODUCTION

- (A) On 13 September 2020 the Parties entered into a supply agreement under which Valneva agreed to supply the Authority with the Product (“*Supply Agreement*”).
- (B) The Parties now wish to vary certain term of the Supply Agreement as set out in this Amendment Agreement.

## IT IS AGREED that:

### 1. DEFINITIONS

1.1 In this Amendment Agreement, words and expressions shall have the same meanings as in the Supply Agreement unless expressly stated otherwise.

1.2 The rules of interpretation set out in clause 1.2 and 1.3 of the Supply Agreement are incorporated herein by reference though set out herein, *mutatis mutandis*.

### 2. AMENDMENTS

2.1 The date of [\*\*\*] in clause 8.2 of the Supply Agreement is deleted and is replaced with [\*\*\*].

2.2 The date of [\*\*\*] in clause (b) at Schedule 7 of the Supply Agreement is deleted and is replaced with [\*\*\*].

### 3. MISCELLANEOUS

3.1 The provisions of clause 35 of the Supply Agreement are incorporated herein by reference as though set out herein, *mutatis mutandis*, provided that this Amendment Agreement together with the Supply Agreement (as amended on the terms herein) constitutes the entire agreement between the Parties as set forth in clause 35.9.

3.2 Save for the amendments to the Supply Agreement as expressly provided for in clause 2 of this Amendment Agreement, no other amendments are made to the Supply Agreement and all other terms and conditions of the Supply Agreement in force as of the Amendment Date will remain in full force and effect and are not affected by this Amendment Agreement.



**\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.**

Execution Version

DATED 30 JANUARY 2021

VALNEVA SE

VALNEVA AUSTRIA GMBH

AND

THE SECRETARY OF STATE FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY

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SECOND AMENDMENT AGREEMENT TO THE  
SARS-COV2 VACCINE SUPPLY AGREEMENT

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THIS AMENDMENT AGREEMENT (“**Second Amendment Agreement**”) is dated 30 January 2021 (“**Amendment Date**”) and made between:

1. **VALNEVA S.E.**, a company registered in France (company number 422,497,560) whose registered address is at 6 rue Alain Bombard 44800 Saint Herblain, France (“**Parent**”); and
2. **VALNEVA AUSTRIA GMBH**, a company registered in Austria (company number FN 389960 x /HG Wien) whose registered address is at Campus Vienna Biocenter 3, 1030 Vienna, Austria (“**Valneva**”); and
3. **THE SECRETARY OF STATE FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY**, acting on behalf of the Crown, whose principal office is at 1 Victoria Street, London, SW1H 0ET (the “**Authority**”), (each a “**Party**”, and collectively the “**Parties**”).

## **INTRODUCTION**

- (A) On 13 September 2020 the Parties entered into a supply agreement under which Valneva agreed to supply the Authority with the Product (“**Supply Agreement**”) that is targeted against the Original Strain (as defined below) and which is known as VAL2001\_Covid19 (“**Original Product**”).
- (B) On 17 December 2020 the Parties entered into an amendment agreement under which the Parties agreed to delay the deadline for the Authority to exercise the Follow On Order to [\*\*\*] (“**First Amendment Agreement**”).
- (C) The Parties now wish to further amend certain terms of the Supply Agreement, as amended by the First Amendment Agreement, as set out in this Second Amendment Agreement in conjunction with the exercise of the Follow On Order to include mechanisms to address future variants through New Vaccines, changes to the Production Schedule and/or Delivery Schedule to provide the Authority with greater flexibility to manage receipt and deployment of the Product, variations to the payment terms for the Follow On Order, and secure assistance from Valneva to re-sell doses of the Product which are not required by the Authority.
- (D) Under the Supply Agreement, the Authority has the right to exercise an option for the Manufacture and Delivery of additional Product pursuant to a Follow On Order. The Authority now wishes to record the valid exercise of its option to such Follow On Order.

## **IT IS AGREED that:**

### **1. DEFINITIONS**

- 1.1 In this Second Amendment Agreement, words and expressions shall have the same meanings as in the Supply Agreement (as amended) unless expressly stated otherwise.
- 1.2 The rules of interpretation set out in clause 1.2 and 1.3 of the Supply Agreement (as amended) are incorporated herein by reference as though set out herein, *mutatis mutandis*.

## 2. AMENDMENTS

With effect from the Amendment Date, the Parties hereby agree that the Supply Agreement (as amended) shall be further amended to reflect and implement the following amendments:

	<u>Reference</u>	<u>Amendment</u>
1.	New Clause 4.21 shall be inserted as follows	<p>“Product Modifications</p> <p>4.21 Without prejudice to the foregoing Development obligations, if a variant to or new strain of (each a “<b>Variant</b>”) the original SARS-CoV-2 coronavirus 2019 virus strain (being that identified as the cause of the pandemic outbreak in early 2020 (“<b>Original Strain</b>”)) is detected and verified by any Governmental Authority as an actual or potential threat, then:</p> <p>4.21.1. the Parties shall, upon written notice, promptly and in good faith discuss and explore the effectiveness of the Original Product on prophylaxis and vaccination against the Variant including as to whether Valneva’s Original Product is shown to be, or is reasonably considered to be, materially less effective or ineffective against such Variant;</p> <p>4.21.2. following, or in conjunction with the discussions under Clause 4.21.1, the Parties shall promptly and in good faith discuss and explore the feasibility of and what would be involved (including the timelines, [***] and impact on the Original Product) in modifying the Original Product and/or [***] a new vaccine product, in each case, to target the Variant for prophylaxis and vaccination against the Variant and/or to improve the effectiveness of the Original Product to target the Variant (each being a “<b>New Vaccine</b>”);</p>



- 4.21.3. the Authority shall have the right, to serve a written notice (each being a “**Variant Notice**”) initiating the process set out in clause 4.21.5 for the [\*\*\*] of each New Vaccine set forth in the Variant Notice;
- 4.21.4. the provisions of clause 4.18 shall apply, mutatis mutandis, to any New Vaccine with references therein to “**Product**” being construed as New Vaccine;
- 4.21.5 upon exercise of a Variant Notice by the Authority: (A) the Parties shall promptly discuss and in good faith and acting reasonably agree (i) a sensible and proportionate [\*\*\*] and Manufacture of the New Vaccine (to be agreed on an equivalent basis to [\*\*\*] for the Follow On Order); (ii) a timeline. [\*\*\*] (by reference to the existing [\*\*\*]) and Manufacturing plan (by reference to the existing Manufacturing Plan) for [\*\*\*] Manufacturing the New Vaccine; (iii) any amendments to this Agreement necessary to give effect to the Parties’ intention for Valneva to undertake the [\*\*\*] Manufacture of the New Vaccine for supply to the Authority upon terms equivalent to (but subject to variation based on the Parties’ agreement on the [\*\*\*] and timeline to be agreed above) the terms for the [\*\*\*], Manufacturing and supply of the Original Product including the substitution of any volume of Original Product that is subject to an Order but pending Delivery for the New Vaccine (being together a “New Vaccine Amendment”); and (B) following agreement of a New Vaccine Amendment. Valneva shall use Commercially Reasonable Efforts to [\*\*\*] Manufacture the New Vaccine for supply under this Agreement.

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For the purposes of this clause 4.21, references to the “**Product**” in the definitions of [\*\*\*] Manufacture (and other definitions used therein) shall be construed, where the context requires, to mean the New Vaccine. Until a New Vaccine Amendment is concluded the Authority shall not be liable to Valneva for any [\*\*\*] Manufacturing activities relating to a New vaccine or pursuant to a variant Notice, and Valneva shall have no obligations to the Authority in that same regard.”

2. New Clause 5.21 shall be inserted as follows

“New Vaccines

5.21 If a New Vaccine is being Developed by Valneva and which has not been the subject of a New Vaccine Amendment, then upon written notice from the Authority pursuant to this clause 5.21 the Parties shall discuss in good faith the right for the Authority to substitute any volume of Original Product that is subject to an Order but pending Delivery for the New Vaccine being so Developed. For the avoidance of doubt, the price of a New Vaccine so Developed is to be the subject of a [\*\*\*] commercial agreement between the Parties, as part of these good faith discussions but having regard to [\*\*\*].

3. Clause 6.4 shall be replaced in its entirety as follows

“6.4 Valneva shall structure and work to its Production Schedule such that it is able to meet the Delivery Schedule and in doing so shall adapt the Production Schedule so as to use Commercially Reasonable Efforts to minimise the time between Manufacture and Delivery of such Product (in accordance with the Delivery Schedule) in order to maximise the remaining shelf life of the Product at the time of Delivery beyond the Minimum Shelf Life. With respect to the Production Schedule:

6.4.1. Valneva shall keep the Authority promptly and regularly informed of, and any updates to, the Production Schedule for the Manufacture of each batch of Product and from which batch each tranche of Product will be Delivered (including the anticipated and actual Manufacturing and Delivery dates);

- 6.4.2. the Authority may notify Valneva, pursuant to this clause 6.4.2, of an intended change to the Delivery Schedule for Product intended to be Manufactured pursuant to one or more notified batch(es). The Authority will seek to provide such notification as early as reasonably possible in the Manufacturing and Delivery process notified to it by Valneva;
- 6.4.3 upon receipt of any notice of intended change, Valneva shall respond as soon as reasonably practicable to report to the Authority the best estimate of [\*\*\*] that will be directly incurred, following Commercially Reasonable Efforts to mitigate the same, as a direct consequence of such intended change to the Production Schedule and/or the Delivery Schedule so requested by the Authority (such [\*\*\*] being [\*\*\*]), which [\*\*\*] shall also be discussed at the Parties' joint [\*\*\*] and [\*\*\*] meeting which reports to the JSC. For the avoidance of doubt, [\*\*\*] shall include in respect of the affected Product [\*\*\*];

6.4.4 the Authority may issue a determinative notice of change pursuant to clause 9.2 (following or in substitution of a notice under clause 6.4.2) whereupon the Production Schedule impacted by such change shall be adjusted as follows:

- (a) if the Authority delays the date of Delivery of Product under the Delivery Schedule then Valneva shall use Commercially Reasonable Efforts to, either (i) delay Manufacture of the applicable batch intended for such Delivery; or (ii) Deliver Product (according to the delayed Delivery Schedule) that has been Manufactured from a later Manufacturing batch; in each case of (i) and (ii) adapting the Production Schedule so as to minimise the time between Manufacture and Delivery of such Product in order to maximise the remaining shelf life of the Product at the time of Delivery beyond the Minimum Shelf Life;
- (b) if the Authority brings forwards Delivery of Product under the Delivery Schedule then Valneva shall use Commercially Reasonable Efforts to either (i) bring forward the commencement of Manufacture of the applicable batch that was intended for such Delivery; or (ii) Deliver Product that is Manufactured from an earlier Manufacturing batch; but in each case of (i) and (ii) adapting the Production Schedule so as to minimise the time between Manufacture and Delivery of such Product in order to maximise the remaining shelf life of the Product at the time of Delivery beyond the Minimum Shelf Life;

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- (c) the Manufacturing Plan and Production Schedule shall be automatically updated to reflect the new commencement dates for the applicable Manufacturing batches affected by such change to the Delivery Schedule; and
- (d) the Authority shall pay to Valneva those [\*\*\*] upon any such change to the Production Schedule and/or Delivery Schedule under this clause 6.4 implemented pursuant to the Authority’s determinative notice.

Subject to clauses 9.1 and 9.2, any other variation to the Delivery Schedule must be via agreement with the JSC.”

- 4. The first sentence of Cause 9.1 shall be replaced in its entirety as follows “The delivery schedule, setting forth the quantities and timing of Delivery of the Regimens of Product pursuant to the Orders, is initially set out in Schedule 7 in respect of the Initial Order and, if exercised, the Follow On Order (as subsequently updated pursuant to this Agreement, the “**Delivery Schedule**”).”
- 5. Clause 9.2 shall be replaced in its entirety as follows “The Delivery Schedule may only be updated and refined during the Term as follows:
  - 9.2.1. in accordance with clause 9.1;
  - 9.2.2. with the agreement of the JSC;
  - 9.2.3. the Authority may bring forward dates for Delivery of Product earlier than in the then current Delivery Schedule by providing Valneva with written notice pursuant to this clause 9.2, being no

less than [\*\*\*] prior to any scheduled Delivery, to the extent that a Minimum Viable Marketing Authorisation or Emergency Use Authorisation has been granted or issued for the Product by such Delivery date (or where not granted supply shall be made under quarantine) and Delivery of such quantities of Product can be Delivered by such earlier date by Valneva using Commercially Reasonable Efforts to do so; and/or

9.2.4. the Authority may delay dates for Delivery of Product to dates later than in the then current Delivery Schedule by providing Valneva with written notice pursuant to this clause 9.2, being no less than [\*\*\*] prior to any scheduled Delivery.

Upon a change to the Delivery Schedule, Valneva shall, if required, update the Production Schedule in accordance with clause 6.4 and notify the Authority of any revised Production Schedule. The Authority' shall pay to Valneva [\*\*\*] in accordance with clause 6.4. Such [\*\*\*] will be subject to the same [\*\*\*] under [\*\*\*] of the Supply Agreement.”

6. Clause 13.5.4 shall be replaced in its entirety as follows

“The Authority shall pay to Valneva against an invoiced issued for:

- (a) [\*\*\*] Target Follow On Order Price [\*\*\*];
- (b) [\*\*\*] Target Follow On Order Price [\*\*\*];
- (c) [\*\*\*] of the Follow On Order but in no event earlier than [\*\*\*] unless otherwise agreed by the Parties, PROVIDED THAT, notwithstanding clause 14.2 such invoice shall be payable within [\*\*\*] rather than [\*\*\*];
- (d) [\*\*\*] Target Follow On Order Price [\*\*\*] PROVIDED THAT such invoice shall not be issued earlier than [\*\*\*] unless the Parties agree otherwise and Delivery pursuant to the Follow On Order shall not be deemed possible until the Initial Order has been Delivered in full; and

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7. New Clause 16.1 and 16.2 shall be inserted as follows, with original Clauses 16.1, 16.2 and 16.3 renumbered respectively as 16.3, 16.4 and 16.5

(e) [\*\*\*] Target Follow On Order Price [\*\*\*].”

“16.1 Subject to 16.1.3, the Authority shall have the right, by written notice to Valneva from time to time specifying the volumes to be resold, to require Valneva to use Commercially Reasonable Efforts to re-sell to other Governmental Authorities or Third Parties such quantities of Product set out in the notice(s) that are the subject of Orders but which, at the time of notice, have not yet been Delivered to the Authority and if it does so:

16.1.1 any resale of the Product by Valneva shall be on behalf of the Authority (to dispose of its allocation of Product) on terms approved by the Authority and shall be at the [\*\*\*] but [\*\*\*] than that [\*\*\*] from time to time;

16.1.2 any amount paid by such other Governmental Authority of Third Party (“**Third Party Receipt**”) shall be received by Valneva on behalf of the Authority and:

(A) Valneva shall pay to the Authority, from any Third Party Receipt, an amount equal to:

(i) [\*\*\*]; and

(ii) if the Third Party- Receipt is greater than [\*\*\*] of the Supply Agreement [\*\*\*]; and

- (iii) if the Third Party Receipt is greater than [\*\*\*] provided that any such payment shall, for the purposes of calculating the [\*\*\*] by Valneva to the Authority;
  - (B) any balance of the Third Party Receipt remaining after the payment of the amounts described in (A) above shall be retained by Valneva [\*\*\*] for the resale.
- 16.1.3 upon any resale, such volume of Product shall be deemed Delivered such that the Price for such Product is payable in full, and any payment received by Valneva on behalf of the Authority and due to the Authority pursuant to clause 16.1.2(A) from such resale may be set off against any outstanding payment due by the Authority for the Product so sold or any portion of the Price to be invoiced as a consequence of such deemed Delivery. For the avoidance of doubt, unless otherwise stated, the [\*\*\*] of the Supply Agreement shall not apply on these resales.
- 16.1.4 upon request, Valneva shall provide the Authority with a detailed breakdown and documentation to evidence any such payments received by it on behalf of the Authority from other Governmental Authorities or Third Parties in connection with the re-sale of any Product. Notwithstanding the foregoing, if despite Valneva's use of Commercially Reasonable Efforts to resell quantities of Product, to the extent any such quantities of Product have not or cannot be re-sold at the time of a written notice from the Authority, then upon receipt of such written notice the Authority shall be entitled to Delivery of the volume of Product set out in such notice (up to the volume that Valneva had not or could not sell) in accordance with the terms of this Agreement.



- 16.2 Provided that the Authority has first paid [\*\*\*] for the Product, the Authority may itself, without Valneva's consent (but subject to clause 16.2.2), re-sell the Product outside of the Territory. If:
- 16.2.1 the Authority re-sells the Product outside the Territory at a price which [\*\*\*] by the Authority, [\*\*\*]; and
- 16.2.2 if the Authority, using Commercially Reasonable Efforts, cannot sell the Product [\*\*\*], then prior to making such re-sale the Authority shall, by written notice, notify Valneva of the quantity [\*\*\*] of the Product that the Authority is proposing to resell. Within [\*\*\*] of such notice:
- (A)if Valneva elects by written notice, it will purchase the quantity of Product [\*\*\*]; or
- (B)if Valneva has not served written notice pursuant to (A), then the Authority may proceed to resell the quantity of Product [\*\*\*].

For the avoidance of doubt, if Valneva elects to purchase any Product under 16.2.2(A), then the provisions of clause 13.19 of the Supply Agreement will not apply to any such Products purchased. ”

**3. EXERCISE OF FOLLOW ON ORDER**

**3.1** Pursuant to Clause 8.2 of the Supply Agreement (as amended), the Authority hereby exercises its Follow On Order and submits an order for twenty million (20m) Regimens of the Product for Delivery in 2022 in accordance with the Delivery Schedule. Valneva hereby acknowledges the effective Follow On Order being placed and that is binding on the Parties. In accordance with Clause 8.2 of the Supply Agreement (as amended), the Authority sets forth details of its order number, VAT number and invoice address below:

Order Number: [\*\*\*]

VAT Number: [\*\*\*]

Invoice Address: [\*\*\*]

**3.2** The Parties hereby agree that the delivery schedule set forth in the Annex to this Second Amendment Agreement is the current Delivery Schedule under the Supply Agreement.

**4. MISCELLANEOUS**

**4.1** The provisions of clause 35 of the Supply Agreement are incorporated herein by reference as though set out herein, *mutatis mutandis*, provided that this Second Amendment Agreement together with the Supply Agreement (as previously amended and as amended on the terms herein) constitutes the entire agreement between the Parties as set forth in clause 35.9.

**4.2** Save for the amendments to the Supply Agreement as expressly provided for in clause 2 of this Second Amendment Agreement and the placing of the Follow On Order pursuant to clause 3 of this Second Amendment Agreement, no other amendments are made to the Supply Agreement and all other terms and conditions of the Supply Agreement in force as of the Amendment Date will remain in full force and effect and are not affected by this Second Amendment Agreement.

**4.3** The Supply Agreement shall be subject to the provisions of this Second Amendment Agreement and where there is any conflict between the provisions of this Second Amendment Agreement and the Supply Agreement, the provisions of this Second Amendment Agreement shall prevail.

**4.4** Nothing in this Second Amendment Agreement or the amendment of the Supply Agreement shall constitute any waiver.

**IN WITNESS WHEREOF**, the Parties have caused this Second Amendment Agreement to be executed in three counterparts by their respective duly authorised representatives as of the date set forth at the beginning of this Second Amendment Agreement.

SIGNED by , )  
Authorised Signatory for and on behalf of )  
**VALNEVA S.E.** )

SIGNED by , )  
Authorised Signatory for and on behalf of )  
**VALNEVA AUSTRIA GMBH** )

SIGNED by , )  
Authorised Signatory for and on behalf of )  
**VALNEVA AUSTRIA GMBH** )

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**THE SECRETARY OF STATE FOR**  
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