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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: October 18, 2021

Commission File Number: **001-40377**

Valneva SE
(Translation of registrant's name into English)

6 rue Alain Bombard
44800 Saint-Herblain, France
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F [X] Form 40-F [ ]

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

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Exhibit

99.1	Press release dated October 18, 2021
99.2	Presentation dated October 18, 2021

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Valneva SE
(Registrant)

Date: October 18, 2021

/s/ Thomas Lingelbach
Thomas Lingelbach
Chief Executive Officer and President

Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001

- **VLA2001 successfully met both co-primary endpoints**
  - Superior neutralizing antibody titer levels compared to active comparator vaccine, AstraZeneca's AZD1222 (ChAdOx1-S)
  - Neutralizing antibody seroconversion rate above 95%
- **VLA2001 induced broad T-cell responses with antigen-specific IFN-gamma-producing T-cells against the S, M and N proteins.**
- **VLA2001 was well tolerated, demonstrating a statistically significant better tolerability profile compared to active comparator vaccine**

Saint Herblain (France), October 18, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced positive topline results from the Phase 3 pivotal trial Cov-Compare of its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001. Valneva's Chief Executive Officer, Thomas Lingelbach, and the trial's Chief Investigator, Adam Finn, Professor of Paediatrics at the University of Bristol, will comment on the results in a live webcast beginning at 3 p.m. CET today. Please refer to this link: https://edge.media-server.com/mmc/p/3zmb7nnp.

The pivotal Phase 3, Cov-Compare trial recruited a total of 4,012 participants aged 18 years and older across 26 trial sites in the United Kingdom. The trial met its co-primary endpoints: VLA2001 demonstrated superiority against AZD1222 (ChAdOx1-S), in terms of geometric mean titer for neutralization antibodies (GMT ratio=1.39, p<0.0001), (VLA2001 GMT 803.5 (95% CI: 748.48, 862.59)), (AZD1222(ChAdOx1-S) GMT 576.6 (95% CI 543.6, 611.7)), as well as non-inferiority in terms of seroconversion rates (SCR above 95% in both treatment groups) at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and older.

T-cell responses analyzed in a sub-set of participants showed that VLA2001 induced broad antigen-specific IFN-gamma producing T-cells reactive against the S- (74.3%), N- (45.9%) and M- (20.3%) protein.

VLA2001 was generally well tolerated. The tolerability profile of VLA2001 was significantly more favorable compared to the active comparator vaccine. Participants 30 years and older reported significantly fewer solicited adverse events up to seven days after vaccination, both with regards to injection site reactions (73.2% VLA2001 vs. 91.1% AZD1222 (ChAdOx1-S), p<0.0001) and systemic reactions (70.2% VLA2001 vs. 91.1% AZD1222 (ChAdOx1-S), p<0.0001). No unsolicited treatment-related serious adverse events (SAE) have been reported. Less than 1% reported an adverse event of special interest in both treatment groups. Participants in the younger age group vaccinated with VLA2001 showed an overall safety profile comparable to the older age group.

The occurrence of COVID-19 cases (exploratory endpoint) was similar between treatment groups. The complete absence of any severe COVID-19 cases may suggest that both vaccines used in the study prevented severe COVID-19 caused by the circulating variant(s) (predominantly Delta).

Adam Finn, Professor of Paediatrics, University of Bristol, Trial Chief Investigator, said: "The low levels of reactogenicity and high functional antibody responses alongside broad T-cell responses seen with this adjuvanted inactivated whole virus vaccine are both impressive and extremely encouraging. This is a much more traditional approach to vaccine manufacture than the vaccines so far deployed in the UK, Europe and North America and these results suggest this vaccine candidate is on track to play an important role in overcoming the pandemic."

Thomas Lingelbach, Chief Executive Officer of Valneva, said: "These results confirm the advantages often associated with inactivated whole virus vaccines. We are committed to bringing our differentiated vaccine candidate to licensure as quickly as possible and continue to believe that we will be able to make an important contribution to the global fight against the COVID-19 pandemic. We are keen to propose an alternative vaccine solution for people who have not yet been vaccinated."

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented: "I would like to thank the trial investigators as well as all trial participants and collaborators, especially the National Institute for Health Research and the clinical teams within the NHS Research Centres as well as Public Health England. This outcome shows the value of the collaboration that we started in September 2020 and we could not have achieved this milestone without them. We'll continue to work very closely with the MHRA to complete our rolling submission for approval."

Valneva commenced rolling submission for initial approval with the UK's Medicines and Healthcare products Regulatory Agency (MHRA) and is preparing to commence rolling submission for conditional approval with the European Medicines Agency. A final assay validation required by the MHRA to verify the integrity of the VLA2001-301 data remains ongoing and is a prerequisite for final submission of the clinical study report.

As part of the product development strategy, Valneva has completed recruitment of 306 volunteers aged 56 years and older in New Zealand[1] into its VLA2001-304 trial and expects topline data in early 2022. Valneva has also announced the start of recruitment of adolescents as an expansion of the Cov-Compare trial[2].

The Company is preparing for trials in children (5-12 years of age) and a Valneva sponsored booster trial to evaluate VLA2001's booster performance for people in need of a booster.

About Phase 3 Trial Cov-Compare (VLA2001-301)

Cov-Compare (VLA2001-301) is a randomized, observer-blind, controlled, comparative immunogenicity trial in 4,012 adults and 660 adolescents. Co-Primary immunogenicity endpoints are superiority of GMT ratio of VLA2001 compared to AZD1222 (ChAdOx1-S) as well as non-inferiority of seroconversion rates of neutralizing antibodies administered in a two-dose immunization schedule four weeks apart, measured at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and older. It also evaluates the safety and tolerability of VLA2001 at two weeks after the second vaccination in adults and adolescents aged 12 years and older. The trial is being conducted at 26 sites across the U.K. 2,972 participants 30 years of age and older were randomized in a 2:1 ratio to receive two intramuscular doses of either VLA2001 (n=1,977) or AZD1222 (ChAdOx1-S) (n=995) at the recommended dose level, 28 days apart, on Days 1 and 29. For immunogenicity analyses, samples from 990 participants (492 vaccinated with VLA2001, 498 vaccinated with AZD1222 (ChAdOx1-S)) who tested sero-negative for SARS-CoV-2 at screening were analyzed. 1,040 participants that are under 30 years of age were recruited in a non-randomized treatment group and received VLA2001 28 days apart. Safety data on those participants 18-29 years of age are analyzed in parallel to the adults 30 years of age and above. Recently, the trial commenced enrolling the first adolescent participants.

About VLA2001

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate against COVID-19 in clinical trials in Europe. It is intended for active immunization of at-risk populations to prevent carriage and symptomatic infection with COVID-19 during the ongoing pandemic and potentially later for routine vaccination including addressing new variants. VLA2001 may also be suited for boosting, as repeat booster vaccinations have been shown to work well with whole virus inactivated vaccines. VLA2001 is produced on Valneva's established Vero-cell platform, leveraging the manufacturing technology for Valneva's licensed Japanese encephalitis vaccine, IXIARO®. VLA2001 consists of inactivated whole virus particles of SARS-CoV-2 with high S-protein density, in combination with two adjuvants, alum and CpG 1018. This adjuvant combination has consistently induced higher antibody levels in preclinical experiments than alum-only formulations and shown a shift of the immune response towards Th1. CpG 1018 adjuvant, supplied by Dynavax Technologies Corporation (Nasdaq: DVAX), is a component of the US FDA- and EMA-approved HEPLISAV-B® vaccine. The manufacturing process for VLA2001, which has already been upscaled to final industrial scale, includes chemical inactivation to preserve the native structure of the S-protein. VLA2001 is expected to conform with standard cold chain requirements (2 degrees to 8 degrees Celsius).

About Valneva SE

Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva has leveraged its expertise and capabilities both to successfully commercialize two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

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This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing, results and completion of research, development and clinical trials for product candidates, relating to regulatory approval of product candidates, and estimates for future performance. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be sustained in the future. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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[1] *Valneva Completes Recruitment of Elderly Participants in Phase 3 Trial of its Inactivated COVID-19 Vaccine.*

[2] *Valneva Continues Expansion of Clinical Trials of Its Inactivated COVID-19 Vaccine Candidate.*

VLA2001 Cov-Compare Topline Results

October 18, 2021

valneva

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Certain information and statements included in this presentation are not historical facts but are forward-looking statements, including statements relating to the business of Valneva, including with respect to the progress, timing, results and completion of research, development and clinical trials for product candidates, relating to regulatory approval of product candidates, and estimates for future performance. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. The forward-looking statements (a) are based on current beliefs, expectations and assumptions, including, without limitation, assumptions regarding present and future business strategies and the environment in which Valneva operates, and involve known and unknown risk, uncertainties and other factors, which may cause actual results, performance or achievements to be materially different from those expressed or implied by these forward-looking statements, (b) speak only as of the date this presentation is released, and (c) are for illustrative purposes only. Investors are cautioned that forward-looking information and statements are not guarantees of future performances and are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Valneva.

Agenda

1. Introduction
2. Cov-Compare Trial and Topline Results
3. VLA2001 Route to Licensure and Development Plan
4. Closing Remarks

INTRODUCTION

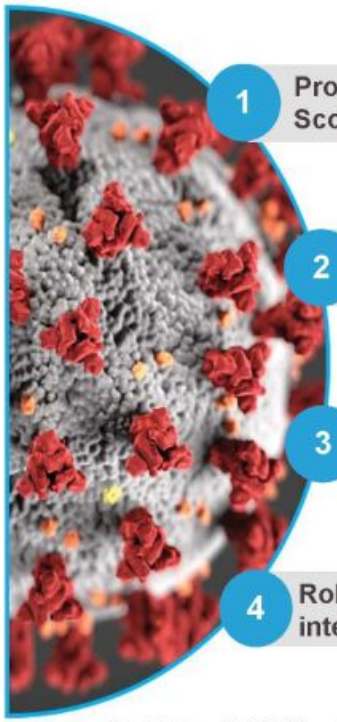
Valneva's Response to the Global COVID-19 Crisis

Well-Known Inactivated Approach Based on Proven Technology

VLA2001:

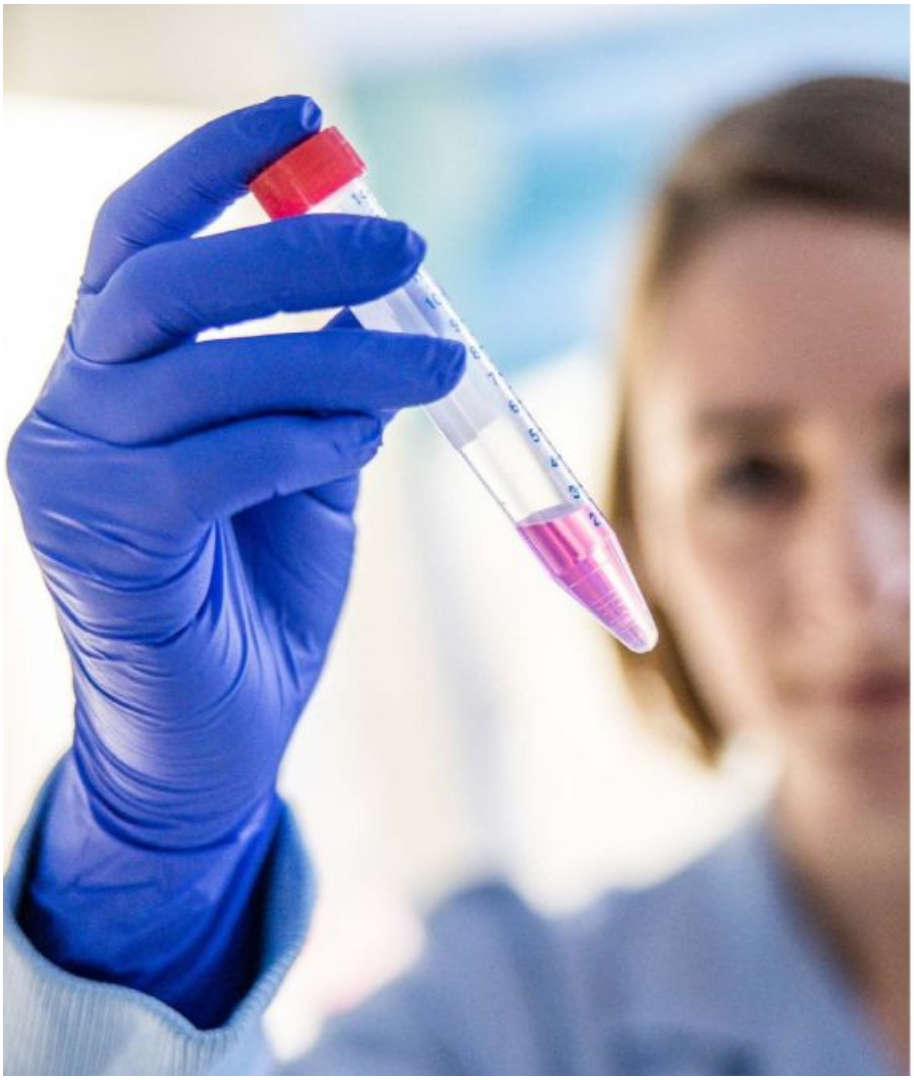
- Inactivated, adjuvanted SARS-Cov 2 whole virus vaccine
- Intended for active immunization of **at-risk populations** to prevent carriage and symptomatic infection with COVID-19 during the **ongoing pandemic** and potentially **later for routine vaccination,** including addressing **new variants**

VLA2001 – The Only Inactivated Vaccine Against COVID-19 in Clinical Development in Europe



1. Program acceleration enabled through use of Valneva's FDA-registered facility in Scotland, where commercial manufacturing commenced January 2021[1]
2. Combines Valneva's proven expertise with inactivated vaccines and Dynavax's advanced CpG 1018 adjuvant[2]
3. Phase 1/2 clinical trial results reported in April 2021[3]
4. Rolling submission to MHRA commenced in Aug. 2021; Phase 3 "Cov-Compare" results intended to form the basis for potential regulatory approval in adults

Note: Photo credit: CDC/Alissa Eckert, MSMI; Dan Higgins, MAM.1 Valneva commences manufacturing of its Inactivated, Adjuvanted COVID-19 vaccine, completes Phase 1/2 study recruitment. 2 Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine; 3 Valneva Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001



COV-COMPARE TRIAL AND TOPLINE RESULTS

About Phase 3 Cov-Compare Trial (VLA2001-301)

- **Randomized, observer-blind, controlled, immunogenicity trial comparing VLA2001 to AstraZeneca's conditionally approved vaccine, AZD1222 (ChAdOx1-S)**

- **2,972 participants 30 years of age and older randomized (2:1) received two doses of either VLA2001 (n=1977) or AZD1222 (ChAdOx1-S) (n=995) at the recommended dose level, 28 days apart**

- **Primary objective: Compare VLA2001 to AZD1222 (ChAdOx1-S) administered as above, to determine:**
  1. Superiority in terms of Geometric Mean Titer ratio of SARS-CoV-2-specific neutralizing antibodies at two weeks after the second vaccination (Day 43) in adults aged 30 years and older; and
  2. Non-inferiority in terms of seroconversion rate and
  3. Frequency and severity of any Adverse Events

- **Also evaluating the safety and tolerability of VLA2001 in additional adults 18-29 years of age (n=1040), two weeks after the second vaccination**

Safety and Tolerability Results - VLA2001 was Well Tolerated

Primary Endpoint:
Frequency and severity of any Adverse Events (AE) up to Day 43 post-vaccination

Overall, 92.0% of participants reported any AE (92.6%, 88.7% and 98.1% in the VLA2001 Under 30 years, VLA2001 30 years and above, and AZD1222 (ChAdOx1-S) groups, respectively).

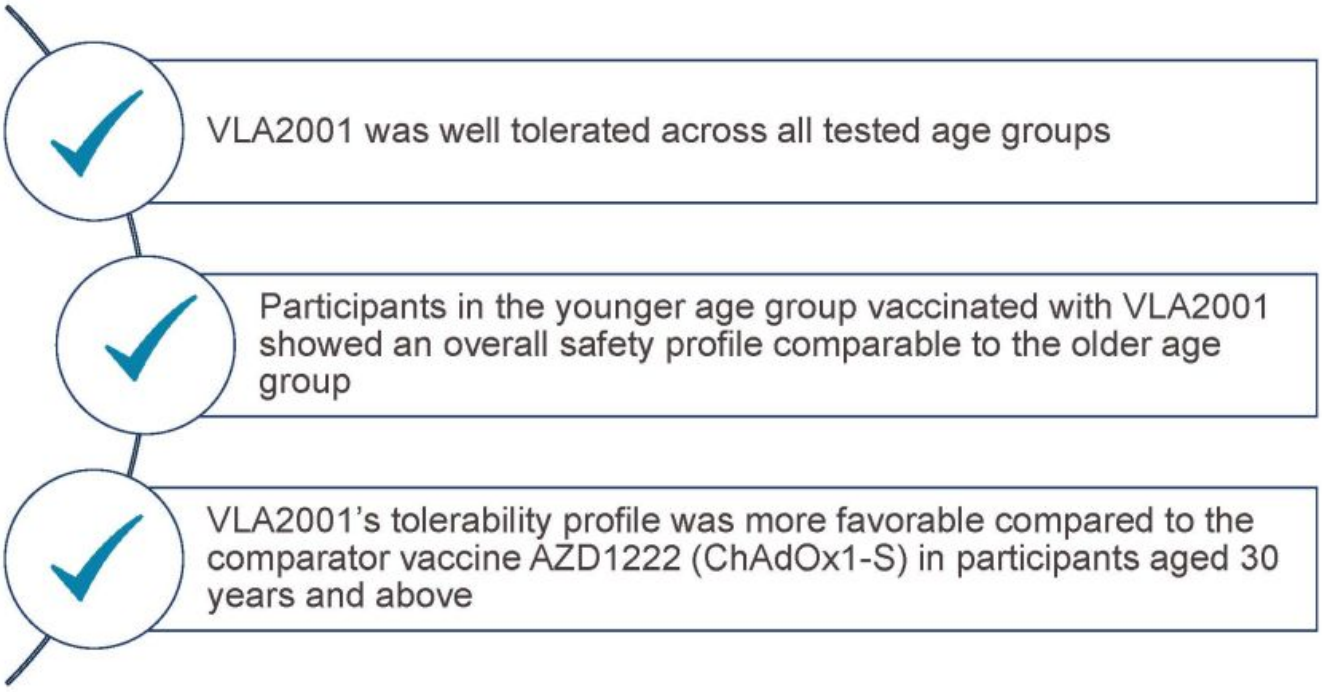
- After any vaccination, statistically significantly fewer participants experienced at least one **solicited Injection Site Reaction:** 73.2% in the VLA2001 (30 years +) group compared to 91.1% in the AZD1222 (ChAdOx1-S) group ($p \leq 0.0001$).

- After any vaccination, statistically significantly fewer participants experienced at least one **solicited Systemic Reaction:** 70.2% in the VLA2001 (30 years +) group compared to 91.1% in the AZD1222 (ChAdOx1-S) group ($p \leq 0.0001$).

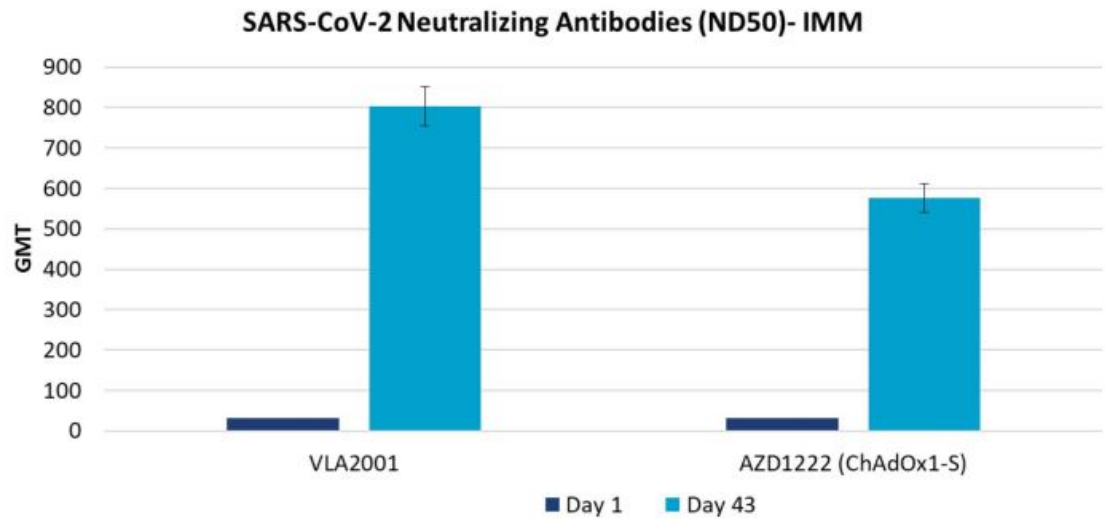
- Statistically significantly fewer participants experienced **any unsolicited AE** (27.9% in the VLA2001 (30 years +) compared to 32.7% in the AZD1222 (ChAdOx1-S) group) ($p = 0.0075$)
  - Rates of participants with **unsolicited serious AEs** (0.3% vs. 0.2%) or medically attended unsolicited AEs (7.2% vs. 6.5%) were comparable between the VLA2001 (30 years +) group and the AZD1222 (ChAdOx1-S) group.
  - No related unsolicited serious AEs have been reported.

- Majority of solicited and unsolicited AEs were mild and moderate.

VLA2001-301 – Preliminary Safety Conclusions



SARS-CoV-2 Neutralizing Antibody Levels (ND50)- IMM – VLA2001 Higher Than AZD1222 at Day 43



IMM includes all **randomized and vaccinated participants of the IMM subset** for the primary endpoint evaluation, **who were SARS-CoV-2 seronegative and have at least one evaluable post-baseline antibody titer** measurement after vaccination. Participants who met the case definition of **confirmed COVID-19** during the study are not **included in the IMM**.

GMT: Geometric Mean Titre, CI: Confidence Interval:

Note: [1] p-value and CI calculated using a two-sided t-test applied to log10 transformed data.

A final assay validation required by the MHRA to verify the integrity of the VLA2001-301 data remains ongoing and is a prerequisite for final submission of the clinical study report.

Immunogenicity Results – Primary Endpoint Met

SARS-CoV-2 Neutralizing Antibodies (ND50)- IMM – VLA2001 1.39 x AZD1222

Co-Primary Endpoint: Ratio of geometric mean titer (IMM population) of SARS-CoV-2-specific neutralizing antibodies, at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and above.

Visit	Statistic	VLA2001 Age 30 and Above (N=492)	AZD1222 (ChAdOx1-S) (N=498)	Overall (N=990)
Day 1	n	492	498	990
	GMT (95% CI)	31.0 (31.00, 31.00)	31.0 (31.00, 31.00)	31.0 (31.00, 31.00)
	GMT Ratio (95% CI)			1.00 (1.00, 1.00)
	p-value [1]			NE
Day 43	n	492	493	985
	GMT (95% CI)	**803.5** (748.48, 862.59)	**576.6** (543.59, 611.66)	680.6 (649.40, 713.22)
	GMT Ratio (95% CI)			**1.39 (1.25, 1.56)**
	p-value [1]			**<.0001**

IMM includes all **randomized and vaccinated participants of the IMM subset** for the primary endpoint evaluation, **who were SARS-CoV-2 seronegative and have at least one evaluable post-baseline antibody titer** measurement after vaccination. Participants who met the case definition of **confirmed COVID-19** during the study are not **included in the IMM**.

GMT: Geometric Mean Titre, CI: Confidence Interval:
Note: [1] p-value and CI calculated using a two-sided t-test applied to log10 transformed data.

Immunogenicity Population, Table 14.3.1.1

High Proportion of Participants With Seroconversion in Terms of Neutralizing Antibodies – PP

Co-primary Endpoint: Seroconversion (PP population) (defined as 4-fold increase from baseline) of SARS-CoV-2-specific neutralizing antibodies, at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and above.

Visit	VLA2001 (N=489) N(%)	AZD1222 (ChAdOx1-S) (N=498) N(%)	Overall (N=987) N(%)
Day 43			
Number of patients with eligible samples at visit	456	449	905
Participants with seroconversion (≥ 4- fold increase)			
n(%)	444 (**97.4**)	444 (**98.9**)	888 (98.1)
95% CI [1]	(0.954,0.986)	(0.974,0.996)	(0.970,0.989)
p-value [2]			0.0911

The Per-Protocol population (PP) will consist of the IMM population subjects who have no major protocol violations that impact the immune response.

[1] Exact 95% Clopper-Pearson confidence interval for proportion.

[2] P value or Two-sided CI is for the difference in proportions (VLA2001-AZD122) of Participants with seroconversion at each particular visit.

\+ Per-Protocol Population, Table 14.3.2.1

VLA2001-301 Immunogenicity Conclusions – Endpoints Met

- The trial **met its co-primary immunogenicity endpoints** at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and above
  - › VLA2001 demonstrated **superiority** against AZD1222 (ChAdOx1-S) in terms of geometric mean titer for neutralizing antibodies as measured by live virus microneutralization assay. (GMT ratio=1.39, p<0.0001) (VLA2001 GMT 803.5 (95% CI: 748.48, 862.59))
  - › VLA2001 demonstrated non-inferiority in terms of seroconversion rates (SCR above 95% in both treatment groups)
- At Day 43, 74.3% of a subset of study participants in the VLA2001 group had T-cells that were reactive against peptide pools spanning the full-length S-protein.
- In addition, in the VLA2001 group 45.9% had T-cells that were reactive against the N-protein and 20.3% against the M-protein.

Overall Clinical Data Conclusions
All Endpoints Achieved

- The trial met its co-primary endpoints. VLA2001 demonstrated:
  - **superiority** against AZD1222 (ChAdOx1-S), in terms of **geometric mean titer** for neutralization antibodies, as well as
  - **non-inferiority** in terms of **seroconversion rates** at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and above.

- **VLA2001 was generally well tolerated**
  - The **tolerability profile** of VLA2001 was **significantly more favorable compared** to the **active comparator** vaccine.
  - Participants **30 years and above** reported **significantly fewer solicited adverse events** up to seven days after vaccination**, both** with regards to **injection site reactions**, and **systemic reactions**
  - Participants in the **younger age group** vaccinated with **VLA2001 showed** an **overall safety profile comparable** to the **older age group.**

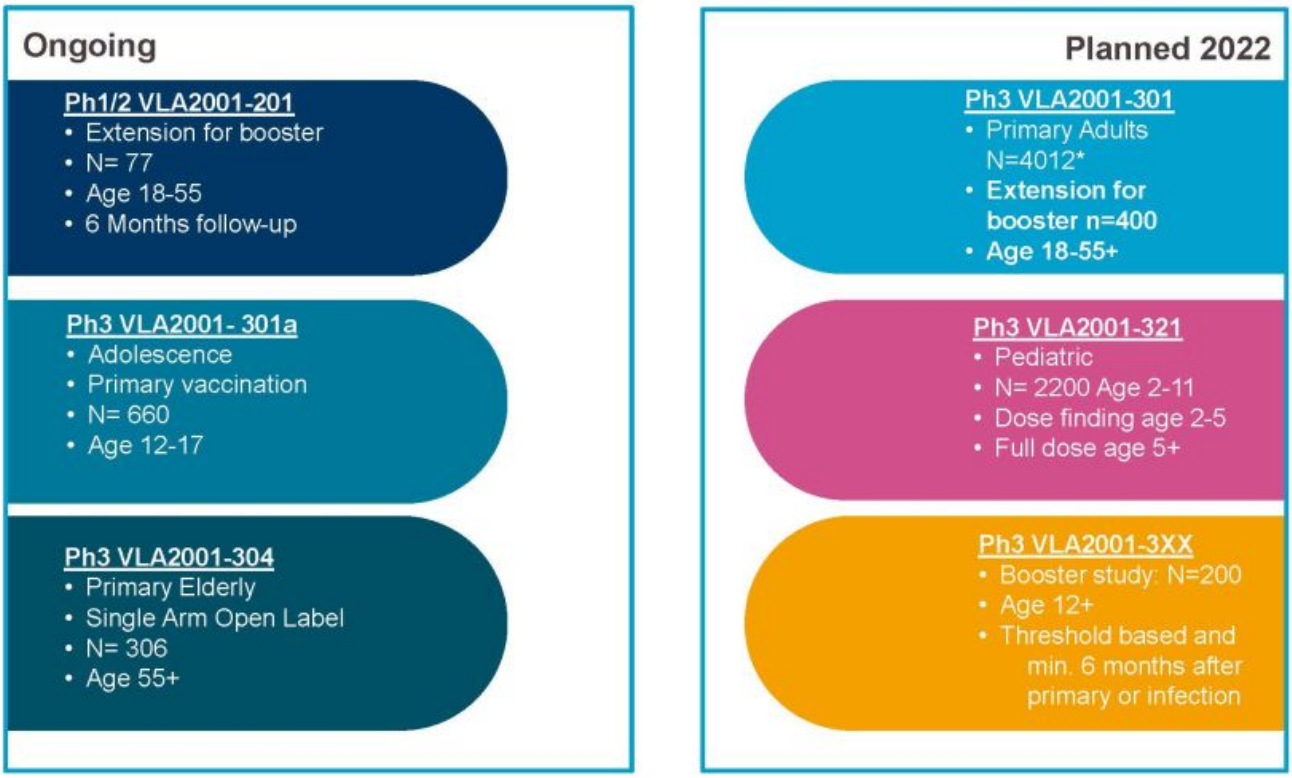
- The **occurrence of COVID-19** cases (exploratory endpoint) was **similar between treatment groups** in the participants **30 years and above.**

- The **complete absence** of **any severe COVID-19 cases** may suggest that **both vaccines** used in the study **prevented severe COVID-19 caused by the circulating variant(s) (predominantly Delta).**

- **T-cell responses** analyzed in a **sub-set of participants** showed that **VLA2001 induced broad** antigen-specific IFN-gamma producing T-cells **reactive against the S, N and M proteins.**

VLA2001 ROUTE TO LICENSURE & DEVELOPMENT PLAN

VLA2001 – SARS-CoV-2 Clinical Development Plan

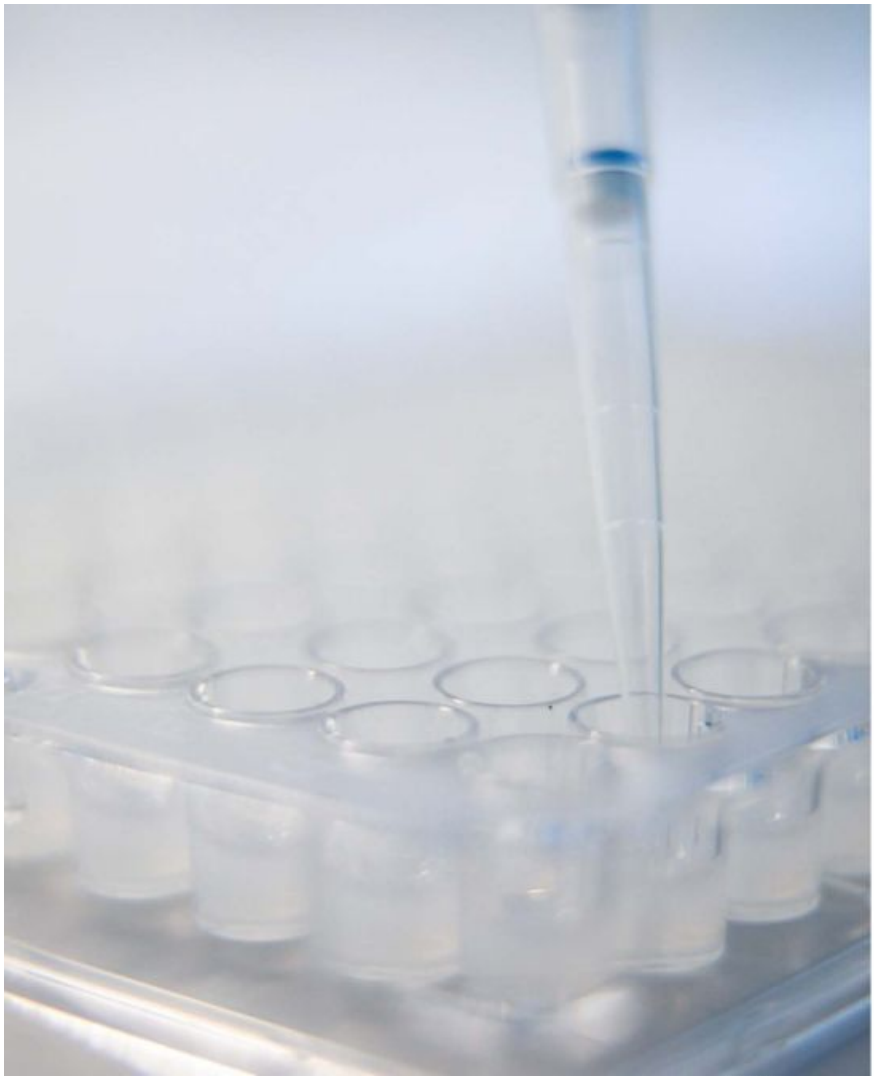


* Primary Adults VLA2001-301 ongoing

VLA2001: Route to Licensure

- **Valneva to submit Cov-Compare data to UK Medicines and Healthcare products Regulatory Agency (MHRA)**
  - Rolling submission with MHRA commenced in August 2021[1]
  - Final submission to MHRA anticipated for November
  - Potential initial approval expected by year-end
- **Valneva plans to submit data package to the European Medicines Agency (EMA)**
  - Pre-submission discussions with EMA ongoing
  - 306 elderly participants in the VLA2001-304 trial already enrolled[2] to collect additional data for the EMA package
  - Cov-Compare endpoints aligned with EMA

1 Valneva Commences Rolling Submission to MHRA for its Inactivated, Adjuvanted COVID-19 Vaccine ; 2 Valneva Completes Recruitment of Elderly Participants in Phase 3 Trial of its Inactivated COVID-19 Vaccine



CLOSING REMARKS

Thank you
Merci
Danke
Tack

valneva