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**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: December 16, 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 [  ]    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):

**Note:** Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

**Note:** Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

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On December 16, 2021, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Exhibit**

[99.1](#)      [Press release dated December 16, 2021](#)

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## 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: December 16, 2021

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

## Valneva Announces Positive Homologous Booster Data for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001

- Initial results show excellent immune response after third dose of VLA2001 administered 7 to 8 months after the second dose of primary vaccination
- Antibody titers increased 42- to 106-fold two weeks after booster dose vs pre-booster levels
- Antibody titers four-fold higher compared to two weeks after primary immunization
- Evaluating sera from boosted participants for cross-neutralization against Variants Of Concern, including Omicron

**Saint Herblain (France), December 16, 2021** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced positive homologous booster data from the Phase 1/2 study, of its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001. Initial results confirm that VLA2001 significantly boosted immunity in participants who received VLA2001 as a primary vaccination.

77 of the 153 original Phase 1/2 study participants, aged 18-55 years, received a booster dose seven to eight months after completion of their primary immunization with either a low, medium or high dose of VLA2001. All participants received a single booster vaccination with VLA2001 at the same (high) dose level used in the pivotal Phase 3 “Cov-Compare” trial.<sup>1</sup> IgG antibody titers (spike protein-based) were measured at the time of the booster as well as two weeks after the booster dose. 45 of the 77 boosted participants were included in the final analysis.<sup>2</sup>

A third dose of VLA2001 elicited an excellent anamnestic response, with similar antibody levels observed whether participants were initially vaccinated with a low, medium or high dose (GMT 9699.3 (95%CI: 8497.76, 11070.71)). This represents a strong boosting effect, increasing levels of antibodies against the Wuhan virus 42- to 106-fold, depending on the pre-boosting levels of antibodies.

Antibody levels measured two weeks after the booster dose were approximately four-fold higher compared to those observed two weeks after primary immunization.

**Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva**, commented: “We are extremely pleased to report our first booster data, confirming that VLA2001 significantly boosted immunity in participants who received VLA2001 as a primary vaccination and regardless of the initial neutralizing antibody level at the time of boosting. Boosting several months, typically six months or more, after primary immunisation is generally effective for inactivated, adjuvanted vaccines. Our teams are working diligently on our rolling review regulatory submissions so that we can quickly deploy our vaccine and ensure it reaches the people who need it. I would like to thank again the trial investigators, participants and collaborators, especially the National Institute for Health Research and the clinical teams within the NHS Research Centres.”

In addition to these initial booster data, Valneva expects to report further homologous booster data from the Phase 3 Cov-Compare study. In parallel, the Company is preparing to launch a dedicated heterologous booster trial, which will evaluate a VLA2001 booster shot provided at least six months after primary vaccination with other vaccines or following natural infection. This study is expected to commence in early 2022.

Valneva will also evaluate the sera from the boosted participants for cross-neutralization against Variants of Concern, including Omicron.

### About Phase 1/2 Trial VLA2001-201

VLA2001-201 is a randomized, dose-finding trial to evaluate the safety, tolerability and immunogenicity of the inactivated, adjuvanted SARS-CoV-2 virus vaccine candidate VLA2001 in healthy subjects. VLA2001-201 is the first-in-human Phase 1/2 trial evaluating three dose levels of VLA2001 (low, medium, high) for safety, tolerability and immunogenicity in a two-dose schedule with intra muscular vaccinations three weeks apart. Overall, 153 healthy young adults aged 18 to 55 years were recruited in the trial. VLA2001-201 is being conducted in two parts: Part A (Day 1 to Day 36) and Part B (Day 37 to Day 208).

77 subjects from the 153 study participants originally included in the Phase 1/2 trial received a booster dose approximately 7-8 months after completion of their primary vaccination series.

### 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<sup>®</sup>. 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.

## Media & Investors Contacts

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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 Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001  
2 27 of the remaining participants who were not included in the final analysis had also received another COVID-19 vaccine, and five experienced a COVID-19 infection during the study.*