**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: August 11, 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): ____

**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.

On August 11, 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 August 11, 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: August 13, 2021

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

**EXHIBIT 99.1**

# Valneva Initiates Further Phase 3 Clinical Trial for its COVID-19 Vaccine Candidate

**Saint-Herblain (France), August 11th, 2021** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, today announced the initiation of a further Phase 3 trial (VLA2001-304) for its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001.

VLA2001-304 aims to generate data in the elderly and is also designed to potentially enable variant-bridging through immune-comparability. Data from this study are expected to complement ongoing clinical trials and support additional regulatory submissions.

VLA2001-304, which will be conducted in New Zealand, will recruit approximately 150 participants aged 56 years and older (Cohort 1) with the aim of generating additional safety and immunogenicity data in this age group following vaccination with VLA2001 (two doses 28 days apart).

**Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva**, said, "The fight against COVID-19 continues and it's extremely important that we continue to gather as much data as possible in all age groups across the population. Everyone should have access to technology best suited to protect them against this virus. We have also been working on Variants of Concern as part of our continued efforts to stay ahead of the virus causing COVID-19 especially since we believe that our inactivated, whole-virus platform will be adaptable across variants. Hence we are extremely pleased to be able to invest in this very important additional clinical trial".

In June 2021, Valneva announced that it had completed recruitment for VLA2001's pivotal Phase 3 trial "Cov-Compare" (VLA2001-301) with over 4,000 randomized participants. Valneva plans to make regulatory submissions for initial approval in the fourth quarter of 2021, subject to successful Cov-Compare data.

**About VLA2001**

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 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 VLA2001-304**

Trial VLA2001-304 will enroll two cohorts. Cohort 1 will include approximately 150 volunteers aged 56 years and older in an open-label manner in order to generate safety and immunogenicity data for this age group. Cohort 2 will include approximately 600 volunteers aged 12 years and older in order to compare immunogenicity data of Valneva's original COVID-19 vaccine candidate, VLA2001, to an additional COVID-19 vaccine candidate, VLA2101, to be based on a variant strain to be confirmed. In both cohorts, vaccinations will be administered in a 2-dose immunization schedule 28 days apart. The trial will be conducted at approximately 10 trial sites in New Zealand.

https://www.clinicaltrials.gov/ct2/show/NCT04956224

ClinicalTrials.gov Identifier: NCT04956224

**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, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. It then applies its deep understanding of vaccine science, including its expertise across multiple vaccine modalities, as well as its established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. The Company 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 & Investor Contacts**

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**Forward-Looking Statements**

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing, design, data read-outs, anticipated results and completion of clinical trials for VLA2001. 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 indicative of future results. 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 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, the ability to obtain or maintain patent or other proprietary intellectual property protection and the impact of the COVID-19 pandemic. 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 this press release as of the date hereof and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.