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: June 3, 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 June 3, 2021, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

(c) Exhibit 99.1. Press release dated June 3, 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: June 4, 2021

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

EXHIBIT 99.1

Valneva Completes Phase 3 Trial Recruitment for its Inactivated COVID-19 Vaccine Candidate

Saint-Herblain (France), June 3, 2021 –Valneva SE, a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, today announced that it has completed recruitment for the pivotal Phase 3 trial of its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001.

Over 4,000 volunteers in the United Kingdom have been randomized in the Phase 3 trial "Cov-Compare" (VLA2001-301), which compares Valneva's SARS-CoV-2 vaccine candidate, VLA2001, against AstraZeneca's conditionally approved vaccine, Vaxzevria[1]. Cov-Compare's primary endpoint is to determine the immune response (Geometric Mean Titer – GMT of SARS-CoV-2-specific neutralizing antibodies) two weeks after completion of a two-dose immunization schedule administered in a four-week interval. Topline data are expected by September 2021 and submission to the UK's Medicines and Healthcare products Regulatory Agency for regulatory approval will follow, subject to the topline data.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "We are extremely pleased to have achieved this important milestone in such a short period of time. I would like to thank the UK Vaccines Taskforce, the National Institute for Health Research and trial sites who have played vital roles in the rapid recruitment and enrollment of volunteers for the clinical trial. Based on our Phase 1/2 clinical data and, assuming successful Phase 3 results, we believe that our inactivated vaccine can make a major contribution to the ongoing fight against the COVID-19 pandemic."

UK Health and Social Care Secretary, Matt Hancock, said, "The UK government has fully supported this promising COVID-19 vaccine by funding the early stage clinical trials and helping to recruit patients through the National Institute for Health Research. I'm delighted to see over 4,000 participants have been recruited rapidly, demonstrating the brilliance of our research teams and the dedication of the public across the UK to beat this virus. Our phenomenal vaccine rollout has shown the strength of our union and this vaccine will be made onshore in Livingston in Scotland which, if approved, will play an important role in protecting our country in the future."

Professor Andrew Ustianowski, National Clinical Lead for the UK NIHR COVID Vaccine Research Programme, said, "The National Institute for Health Research and each of the research sites we support across the UK have worked tirelessly over the past two months to help recruit to his important study. Calling on the hundreds of thousands of members on the NHS COVID-19 Vaccine Research Registry, and various other channels, it is great to see this phase 3 study has reached its recruitment target. All of the participants involved in each phase of the Valneva vaccine studies are playing a key role in helping us understand how the study vaccine will perform in a large population, and hopefully provide us with another effective vaccine in our defence against coronavirus."

VLA2001 is currently the only inactivated vaccine candidate in clinical trials against COVID-19 in Europe. Valneva recently announced that it is participating in the world's first COVID-19 vaccine booster trial in the UK[2]. The COV-Boost trial will look at seven different COVID-19 vaccines and provide vital data on how effective a booster of each vaccine is in protecting individuals from the virus. Initial findings for the COV-Boost study are expected in September 2021.

About Phase 3 Trial Cov-Compare (VLA2001-301)
Cov-Compare (VLA2001-301) is a randomized, observer-blind, controlled, comparative immunogenicity trial in over 4,000 adults.
Primary objectives are to demonstrate the superiority of VLA2001 compared to Vaxzevria administered in a two-dose immunization schedule four weeks apart, in terms of Geometric Mean Titer ratio of SARS-CoV-2-specific neutralizing antibodies at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and older. It will also evaluate the safety and tolerability of VLA2001 at two weeks after the second vaccination in adults aged 18 years and older.
The trial is conducted at 26 sites in the U.K. Approximately 3,000 participants 30 years of age and older have been randomized in a 2:1 ratio to receive two intramuscular doses of either VLA2001 (n=2,000) or Vaxzevria (n=1,000) at the recommended dose level, 28 days apart, on Days 1 and 29. For immunogenicity analyses, samples from approximately 1,200 participants (600 per group) who have been tested sero-negative for SARS-CoV-2 at screening will be analyzed. Approximately 1,000 participants that are under 30 years of age have been placed in a non-randomized treatment group and will receive VLA2001 28 days apart.

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 inactivation with BPL 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. We take 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. We then apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, as well as our established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. We have leveraged our 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.

Valneva Investor and Media Contacts

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Valneva Forward-Looking Statements
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 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 *Approved by MHRA under reg. 174 and by the European Commission as conditional approval*
2 *Valneva to Participate in the World's First COVID-19 Vaccine Booster Trial in the UK*