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Valneva Initiates Phase 3 Clinical Trial for its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001

Saint-Herblain (France), April 21, 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 it has initiated a pivotal Phase 3 clinical trial for its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001.

The Phase 3 trial "Cov-Compare", (VLA2001-301), will compare Valneva's SARS-CoV-2 vaccine candidate, VLA2001, against AstraZeneca's conditionally approved vaccine, Vaxzevria[1], in a comparative immunogenicity trial.

Approximately 4,000 participants will receive two doses of either vaccine. The primary endpoint of Cov-Compare will be 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. The trial is powered to demonstrate superiority of VLA2001 in terms of GMT ratio (VLA2001/Vaxzevria). The trial will be conducted in the U.K. and is supported by the National Institute for Health Research (NIHR).

Adam Finn, Chief investigator for the VLA 2001-301 program, **Professor of Paediatrics at the University of Bristol and Consultant at the Bristol Royal Hospital for Children** said, *"Following very encouraging safety and immune response results from our Phase 1/2 trial, along with my investigator colleagues, I am really looking forward to starting on this important next stage of the clinical development of this important new vaccine. We definitely need more vaccines to help us out of this pandemic and this one is a very promising candidate."*

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "*This Phase 3 initiation marks a significant milestone in the development of the only inactivated vaccine candidate against COVID-19 in clinical trials in Europe. As COVID-19 continues to impact people's daily lives, we remain fully focused on developing another safe and efficacious vaccine solution. We believe that VLA2001 has an important role to play including boosters or potential modifications to the vaccine to address variants. While Cov-Compare is progressing we are planning to conduct additional, complementary trials."*

UK Minister for COVID-19 Vaccine Deployment, Nadhim Zahawi, added*, "The UK has been at the forefront of cutting-edge innovation throughout this pandemic, with Valneva's vaccine set to be made in Scotland, if approved. We have an incredible infrastructure in place for trialing these extraordinary medical advances, and I am delighted the UK will be home to another promising vaccine trial. I've taken part in a vaccine clinical trial myself and would urge all those thinking about signing up to go for it, and to play a part in helping protect your loved ones and saving lives."*

The initiation of the Cov-Compare trial follows the announcement of initial results from Valneva's Phase 1/2 clinical trial, which demonstrated that the safety profile and immunogenicity were supportive of further development[2]. Subject to successful Phase 3 data, Valneva aims to make regulatory submissions for initial approval in the autumn of 2021.

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[1] *Approved by MHRA under reg. 174 and by the European Commission as conditional approval*
[2] *Valneva Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001*

About the Novel Coronavirus SARS-CoV-2 and COVID-19 Disease
SARS-CoV-2 is a new coronavirus identified in late 2019 and belongs to a family of enveloped RNA viruses that include MERS and SARS, both of which caused serious human infections of the respiratory system. The virus, which causes a disease named COVID-19, has never before been found in humans. Since this outbreak was first reported, the virus has caused millions of deaths globally[3]. It has been declared a pandemic by the World Health Organization (WHO).

About Phase 3 Trial Cov-Compare (VLA2001-301)
Cov-Compare (VLA2001-301) is a randomized, observer-blind, controlled, comparative immunogenicity trial in approximately 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 will be conducted at approximately 25 sites in the U.K. Approximately 3,000 participants 30 years of age and older will be 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 will be placed in a non-randomized treatment group and 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).

[3] *https://www.worldometers.info/coronavirus/*

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.

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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.