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Valneva Advances Booster Phase of Cov-Compare Trial of Its Inactivated COVID-19 Vaccine Candidate

Saint-Herblain (France), January 25, 2022 – Valneva SE, a specialty vaccine company, today announced the start of booster vaccinations in adult participants from its Phase 3 pivotal trial, Cov-Compare. This booster extension is intended to provide both homologous and first heterologous booster data to complement previous positive Phase 1/2 booster results. The data are not intended for the initial regulatory approval process which the Company expects to finalize in the coming weeks.

The trial extension will evaluate a booster dose of VLA2001 in adults, aged 18 and above, who received primary vaccination with two doses of VLA2001, as well as participants, aged 30 and above, who received two doses of AstraZeneca's (AZD1222). The VLA2001 booster vaccination will be given at least seven months after completion of the primary vaccination series. The trial is currently ongoing in the UK and is supported by the National Institute for Health Research (NIHR). It is expected to provide topline data during the second quarter of 2022.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "While we are focused on completing our rolling submissions for initial regulatory approval of VLA2001 in a primary vaccination context, we are working extremely hard in parallel to generate further data for VLA2001 in order to assess the role it could play in a booster context as well. We continue to believe that VLA2001 may play an important role to fight the current pandemic phase and beyond. We would like to thank all those who are demonstrating continued interest in our vaccine, and we remain fully committed to bring our inactivated solution to the market as soon as we can."

Valneva announced first positive homologous booster results at the end of December 2021[1]. The data showed an excellent immune response after a booster dose of VLA2001 administered seven to eight months after the second dose of primary vaccination. In addition, Valneva plans to initiate a further dedicated heterologous booster only trial of VLA2001 in the coming weeks. Valneva also recently reported laboratory results demonstrating that serum antibodies induced by three doses of VLA2001 neutralize the initial SARS-CoV-2 virus as well as the Omicron and Delta variants[2].

Valneva is continuing to provide data to the European Medicines Agency (EMA) as well as the UK and Bahraini agencies (MHRA and NHRA respectively), and expects to complete these rolling submissions in time to receive potential regulatory approvals in the first quarter of 2022.[3]

About the Booster extension of Phase 3 Cov-Compare Study VLA2001-301
Cov-Compare is a randomized, observer-blind, controlled, comparative immunogenicity study for which Valneva reported positive topline data in October 2021. As part of the study's booster extension, all participants are offered a third vaccination, except those who already received a licensed COVID-19 vaccine outside of the study. Participants will receive a VLA2001 shot at least seven months after completion of the primary vaccination series with VLA2001 or AZD1222; follow-up visits will be performed 14 days and six months after the booster vaccination. Participants who will not receive a VLA2001 booster vaccination will continue with their scheduled Month 12 follow up visit. In addition to evaluating tolerability of a VLA2001 booster dose, blood samples will be taken for immunogenicity

[1] *Valneva Announces Positive Homologous Booster Data for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001*
[2] *Valneva's Inactivated COVID-19 Vaccine Candidate Shown to Neutralize Omicron Variant – Valneva*
[3] *Valneva Confirms Clinical Trial and Regulatory Submission Timelines for its Inactivated COVID-19 Vaccine Candidate VLA2001*

analysis from a subset of adults who received primary vaccination with two doses of VLA2001, as well as from a subset of participants who received two doses of AZD1222 for primary immunization.

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. VLA2001's manufacturing process, 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 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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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.