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Valneva Initiates Heterologous Booster Trial of Inactivated, COVID-19 Vaccine Candidate

Saint-Herblain (France), May 4, 2022 – Valneva SE, a specialty vaccine company, today announced the initiation of a heterologous booster trial of its inactivated whole-virus COVID-19 vaccine candidate VLA2001. The VLA2001-307 trial will be the Company's first clinical trial to provide booster data following primary vaccination with an mRNA vaccine or natural COVID-19 infection. Data, if positive, could support potential use as heterologous booster, subject to applicable regulatory recommendations and approvals.

The VLA2001-307 trial is expected to include approximately 150 participants who will receive a VLA2001 booster vaccination at least six months after primary vaccination with a licensed mRNA COVID-19 vaccine or following natural COVID-19 infection. The trial will be conducted in the Netherlands and topline results are expected in the third quarter of 2022.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "This trial is extremely important as it will provide the first booster data in unvaccinated adults following natural COVID-19 infection. It will also provide data on VLA2001's capability for use as a heterologous booster and could potentially nicely complement the positive homologous booster data we already generated. We would like to thank all those who are demonstrating continued interest in our vaccine; we remain fully committed to bring our inactivated solution to as many people as we can."

Valneva announced positive homologous booster results at the end of December 2021[1]. The data showed an excellent immune response after a third dose of VLA2001 administered seven to eight months after the second dose of primary vaccination with VLA2001. The third dose of VLA2001 showed a strong boosting effect, increasing levels of binding antibodies against the Wuhan virus 42- to 106-fold, depending on the pre-boosting levels of antibodies. In April 2022, VLA2001 was granted Conditional Marketing Authorization by the UK Medicines and Healthcare products Regulatory Agency ("MHRA") for primary immunization in adults 18 to 50 years of age[2]. This authorization followed emergency use authorization from the Bahraini NHRA in March 2022[3]. The Company is still in a rolling review process with the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") and remains focused on achieving a Conditional Marketing Authorization for VLA2001 in the European Union this quarter.

About Trial VLA2001-307

VLA2001-307 is a multicenter, open-label, single-arm clinical study investigating the safety, tolerability and immunogenicity of a VLA2001 booster vaccination in participants aged 18 years and older. Approximately 150 participants, either generally healthy or with a stable medical condition, will be enrolled in the trial. The VLA2001 booster will be given to adults 6 to 12 months after completion of primary vaccination with an mRNA COVID-19 vaccine or unvaccinated adults 6 to 12 months after PCR confirmation of natural SARS-CoV-2 infection.

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[1] *Valneva Announces Positive Homologous Booster Data for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001*
[2] *Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva*
[3] *Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva*

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.