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Valneva Confirms Clinical Trial and Regulatory Submission Timelines for its Inactivated COVID-19 Vaccine Candidate VLA2001

Saint Herblain (France), January 6, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today confirms the previously communicated timelines of its clinical trials and regulatory submissions for its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001.

As announced in December 2021[1], the Company commenced rolling submissions for initial approval of VLA2001 with the European Medicines Agency, the UK MHRA and the Bahraini NHRA, and is continuing to work closely with those authorities to complete their review process following its positive Phase 3 trial results[2]. Valneva continues to expect potential regulatory approvals in the first quarter of 2022[1].

The Company also announced positive homologous booster results at the end of December 2021[3]. 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. Valneva is also evaluating the sera from the boosted participants for cross-neutralization against Variants of Concern, including Omicron. In parallel, the Company is preparing to launch a dedicated heterologous booster trial, which will evaluate a VLA2001 booster shot provided at least six months after primary vaccination with licensed COVID-19 vaccines or following natural COVID-19 infection.

VLA2001 is also being evaluated in elderly and adolescent volunteers. The Company expects to report topline data for the elderly trial in the coming weeks.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, “In recent weeks, we have been receiving even more messages every day from people around the world who would like to be vaccinated with an inactivated vaccine and want to know more about VLA2001. We continue to believe that our inactivated vaccine candidate could be an important component of the fight against COVID-19, and Valneva remains fully committed to bringing VLA2001 to people who need it as soon as we can. We look forward to sharing further data in due course.”

Valneva announced in November 2021 that the European Commission signed an agreement for the Company to supply up to 60 million doses of VLA2001 over two years – including 24.3 million doses in 2022[4]. Delivery of the vaccine is currently expected to begin in April 2022, subject to approval by the EMA.

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

[1] *Valneva Confirms Initiation of Rolling Review with EMA and Provides Updates on its COVID-19 Vaccine Program VLA2001*
[2] *Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001*
[3] *Valneva Announces Positive Homologous Booster Data for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001*
[4] *Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001*

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.