

## Valneva's Inactivated COVID-19 Vaccine Candidate Shown to Neutralize Omicron Variant

- ***Preliminary laboratory studies demonstrate that three doses of Valneva's inactivated COVID-19 vaccine candidate VLA2001 induced neutralization of the Omicron variant (B.1.1.529 lineage)***
- ***100% of tested serum samples presented neutralizing antibodies against the ancestral virus and Delta variant, and 87% against the Omicron variant***

**Saint Herblain (France), January 19, 2022** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced results from an initial laboratory study demonstrating that serum antibodies induced by three doses of Valneva's inactivated COVID-19 vaccine candidate, VLA2001, neutralize the Omicron variant.

Sera from 30 participants in the Phase 1/2 trial VLA2001-201 were used in a pseudovirus assay to analyze neutralization of the ancestral SARS-CoV-2 virus as well as the Delta and Omicron variants.

All 30 samples (100%) presented neutralizing antibodies against the ancestral virus and Delta variant, and 26 samples (87%) presented neutralizing antibodies against the Omicron variant. The mean fold reduction of neutralization relative to the ancestral virus was 2.7-fold for Delta and 16.7-fold for Omicron.

**Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva**, commented, "We are extremely pleased with these results, which confirm the potential for broad-spectrum protection of our inactivated, adjuvanted whole virus vaccine and its ability to address currently circulating variants of concern. These results add to earlier findings from our Cov-Compare Phase 3 trial, in which two doses of VLA2001 given as a primary vaccination were shown to induce superior neutralizing antibody levels and a broad T-cell response. We continue to believe that VLA2001 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."

Valneva is continuing to provide data to the European Medicines Agency (EMA), the UK Medicines and Healthcare products Regulatory Agency, and the National Health Regulatory Authority in Bahrain (NHRA) as part of the rolling submissions process for initial approval of VLA2001. The Company continues to expect to complete these submissions in time to receive potential regulatory approvals in the first quarter of 2022.<sup>1</sup>

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<sup>2</sup>. Delivery of the vaccine in Europe is currently expected to begin in April 2022, subject to

<sup>1</sup> [Valneva Confirms Clinical Trial and Regulatory Submission Timelines for its Inactivated COVID-19 Vaccine Candidate VLA2001](#)

<sup>2</sup> [Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001](#)

approval by the EMA. Valneva also announced in December 2021 that it had signed an agreement to supply one million doses of VLA2001 to the Kingdom of Bahrain, with deliveries planned in the first quarter of 2022 subject to approval from the Bahraini NHRA.<sup>3</sup>

### **About Valneva's Cross-Neutralization Laboratory Studies**

Neutralization of the currently circulating variants of concern, Delta and Omicron, induced by vaccination with VLA2001 was tested using a pseudovirus neutralization assay. The tested sera were collected from participants in Valneva's Phase 1/2 trial, VLA2001-201, two to four weeks after receiving a booster dose of VLA2001. The booster dose had been administered seven to eight months after the second dose of the priming schedule.

To assess neutralization, pseudoviruses expressing the spike (S) protein from either the ancestral SARS-CoV-2 virus, the Delta variant, or the Omicron variant were pre-incubated with serial dilutions of individual serum samples and then used to infect target cells. Neutralization was calculated from the reduction of infection efficiency at different serum dilutions compared to a no serum control. The assays and analyses were performed by the German Primate Center (Deutsches Primatenzentrum).<sup>4</sup>

### **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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<sup>3</sup> [Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001](#)

<sup>4</sup> For further details of the method, please see Hoffmann et al, Cell 2021 Apr 29; 184(9):2384-2393.



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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 of VLA2001 and with respect to possible regulatory approval of 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.

