

Valneva Commences Manufacturing of its Inactivated, Adjuvanted COVID-19 Vaccine, Completes Phase 1/2 Study Recruitment

- Vaccine production initiated to optimize timeline for potential deliveries
- Phase 1/2 clinical study now fully enrolled; initial data read out expected in April 2021

Saint-Herblain (France), January 28, 2021 – Valneva SE, a specialty vaccine company focused on prevention of infectious diseases with significant unmet medical need, today announced it has commenced production of its inactivated, adjuvanted COVID-19 vaccine candidate in parallel to the ongoing clinical studies, in order to optimize the timeline for potential deliveries of the vaccine. The Phase 1/2 clinical study is now fully enrolled and is expected to report initial results in April 2021.

VLA2001 is currently the only inactivated vaccine candidate in clinical trials against COVID-19 in Europe. A total of 150 healthy adults aged 18 to 55 years have been recruited for the Phase 1/2 study which commenced mid December 2020¹.

Thomas Lingelbach, Chief Executive Officer of Valneva, said, “We are extremely pleased to have achieved these two important milestones in such a short period of time. Our team in Scotland have done an amazing job to get manufacturing started so quickly. I would like to thank the UK Vaccines Taskforce and National Institute for Health Research who have played vital roles in the rapid recruitment and enrollment of the volunteers for the clinical study. We believe that our vaccine, assuming successful development, can make a major contribution in the UK and beyond.”

In September 2020, Valneva announced a major COVID-19 vaccine partnership with the UK government for the supply of up to 190 million doses of its COVID-19 vaccine VLA2001². Under this partnership agreement, if vaccine development is successful, Valneva will provide the UK government with 60 million doses in the second half of 2021. Valneva also announced in January 2021³ it is in advanced discussions with the European Commission for the supply of up to 60 million doses of 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 over 2 million reported deaths globally. It has been declared a pandemic by the World Health Organization (WHO).

About VLA2001

VLA2001 is Valneva’s vaccine candidate against the SARS-CoV-2 virus. 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

¹ [Valneva Initiates Phase 1/2 Clinical Study of Inactivated, Adjuvanted COVID-19 Vaccine](#)

² [Valneva Announces Major COVID-19 Vaccine Partnership with U.K. Government](#)

³ [Valneva in Advanced Discussions with European Commission to Supply up to 60 Million Doses of Inactivated, Adjuvanted COVID-19 Vaccine Candidate](#)



levels in preclinical experiments than alum-only formulations and shown a shift of the immune response towards Th1. VLA2001 is produced on Valneva's established Vero-cell platform, leveraging the manufacturing technology for Valneva's licensed Japanese encephalitis vaccine, IXIARO®. The process, which has already been upscaled to final industrial scale, includes inactivation with BPL to preserve the native structure of the S-protein. CpG 1018 is a component of the US FDA-approved HEPLISAV-B® vaccine and received positive CHMP on December 10, 2020. VLA2001 is expected to conform with standard cold chain requirements (2 degrees to 8 degrees Celsius).

About VLA2001-201

VLA2001-201 is the first-in-human Phase 1/2 study evaluating three dose levels of VLA2001 (low, medium, high) for safety, tolerability and immunogenicity in a two-dose schedule with intra muscular vaccinations three weeks apart. Overall, 150 healthy young adults aged 18 to 55 years have been recruited. The study, which included an open-label dose-escalation phase, is now fully enrolled and is expected to report initial results in April 2021. VLA2001-201 is conducted in two parts: Part A (Day 1 to Day 36) and Part B (Day 37 to Day 208). Following an evaluation of Part A data (i.e., data up to Day 36) from the present study, further clinical studies may be initiated.

About Valneva SE

Valneva is a specialty vaccine company focused on prevention of infectious diseases with significant unmet medical need. The Company has several vaccines in development including unique vaccines against Lyme disease, COVID-19 and chikungunya. Valneva's portfolio includes two commercial vaccines for travelers: IXIARO®/JESPECT® indicated for the prevention of Japanese encephalitis and DUKORAL® indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the U.S. with over 500 employees.

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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.

