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Valneva Initiates Phase 1/2 Clinical Study of Inactivated, Adjuvanted COVID-19 Vaccine Candidate

Saint-Herblain (France), December 16, 2020 – Valneva SE, a specialty vaccine company focused on prevention against diseases with major unmet needs, today announced the initiation of a Phase 1/2 clinical study for its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001.

VLA2001 leverages the manufacturing platform of Valneva's licensed Japanese encephalitis vaccine, IXIARO® and is the first publicly announced inactivated vaccine against COVID-19 to commence clinical development in Europe.

The VLA2001-201 study is a randomized, double blind trial evaluating the safety and immunogenicity for three dose levels in approximately 150 healthy adults.

The study will be conducted in study sites across the United Kingdom and is supported by the National Institute for Health Research (NIHR).

The primary endpoint read-out will be two weeks after completion of the two-dose primary immunization (day 0, 21). Subject to analysis of this data, including the selection of the optimal dose currently expected in the early second quarter of 2021, additional trials are expected to commence immediately thereafter.

The Company currently plans to include more than 4,000 participants in additional trials, which it believes could support an initial regulatory approval as soon as the fourth quarter of 2021.

Alok Sharma, UK Secretary of State for Business, Energy and Industrial Strategy, said, "As we take the monumental steps in rolling out the first COVID-19 vaccine, we must remember that we need to have a range of vaccines available to protect the British public now and long into the future. Today, we have more welcome news that life-saving clinical trials will begin across the country to test the safety and effectiveness of Valneva's vaccine, which is being clinically developed right here in the UK. Having visited Valneva's state-of-the art facility in the summer, I have seen first-hand the incredible work our scientists and researchers are doing to develop this vaccine. Thanks to significant investment from the UK government, we are doing all we can to ensure our country has the capabilities in place to produce hundreds of millions of doses of this vaccine for the UK, and for those around the world."

Thomas Lingelbach, Chief Executive Officer of Valneva, added, "Our teams have been working extremely hard to develop our differentiated vaccine candidate and I would like to thank them, as well as the UK government, for their dedication and support. While conducting our first clinical trials, we are already ramping-up our manufacturing capacities and commencing production at full-scale so that we can make the vaccine widely available across the world assuming the vaccine is safe and effective."

Adam Finn, Chief investigator for the VLA 2001-201 program, **Professor of Paediatrics at the University of Bristol and Consultant at the Bristol Royal Hospital for Children** said, "I'm very pleased and proud to be leading the clinical trials effort to bring this vaccine forward in the UK working alongside a very strong team across several National Institute for Health Research NHS sites. The effort to produce vaccines to prevent COVID-19 and to limit its spread within populations has included several very new approaches, but there are tried and tested approaches to developing highly effective and safe vaccines that we can also use. Growing the whole virus and then inactivating it to make a

vaccine is an approach first developed in the 1950s and has contributed to disease prevention over many decades. We expect this inactivated vaccine containing two adjuvants could generate a broader immune response."

In September 2020, Valneva announced a major COVID-19 vaccine partnership with the U.K. government. Under the agreement, if vaccine development is successful, Valneva will provide the UK government with 60 million doses in the second half of 2021 and UK government has options over provision of a further 130 million doses from 2022-2025. UK government is also investing up-front in the scale up and development of the vaccine, with the investment being recouped against the vaccine supply.

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 1.6 million reported deaths globally. It has been declared a pandemic by the World Health Organization (WHO).

About VLA2001-201

VLA2001-201 is the first-in-human Phase 1/2 study that will evaluate 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 will be recruited. The study will start with an open-label dose-escalation phase. Following review of safety data by an independent Data Safety Monitoring Board (DSMB), the study will be conducted as a randomized, double-blind, multicenter study. 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 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 levels in preclinical experiments than alum-only formulations and shown a shift of the cellular 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.

VLA2001 vaccine is expected to conform with standard cold chain requirements (2 degrees to 8 degrees centigrade).

About Valneva SE

Valneva is a specialty vaccine company focused on prevention against diseases with major unmet needs. 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. The Company has various

vaccines in development including unique vaccines against Lyme disease, chikungunya and COVID-19. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with over 500 employees. For more information, visit www.valneva.com and follow the Company on LinkedIn.

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Valneva Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. 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 their in the future. 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 largely 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, and the ability to obtain or maintain patent or other proprietary intellectual property protection. 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 these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.