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Valneva Switches Focus to Bilateral Discussions to Supply its Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001

Saint-Herblain (France), April 20, 2021 – Valneva SE, a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, today announced it is now focusing on bilateral discussions, on a country by country basis, to supply its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001, and is consequently deprioritizing the ongoing centralized discussions with the European Commission (EC).

This follows the recent announcement on April 6, 2021 of positive initial results from the Phase 1/2 clinical trial of VLA2001[1].

Valneva previously announced the advanced stage of its discussions, which started in the third quarter of 2020, with the EC on January 12, 2021[2]. In September 2020, Valneva announced a collaboration with the UK government to provide up to 190 million doses of VLA2001 through 2025[3], of which 100 million doses have already been ordered.

Thomas Lingelbach, Chief Executive Officer of Valneva, said, "We've committed significant time and effort to try to meet the needs of the central EC procurement process. Despite our recent clinical data, we have not made meaningful progress and have not yet secured a supply agreement. We are therefore now focusing our efforts on those European Union member states, and interested parties outside the EU, who would like to include our inactivated approach within their vaccination strategy. We are convinced that VLA2001 has an important role to play in the future, including boosters or potential modifications to the vaccine to address variants".

Valneva has the only inactivated vaccine candidate in clinical trials against COVID-19 in Europe and is preparing a pivotal, comparative immunogenicity Phase 3 clinical trial expected to commence by the end of April 2021 with the aim of making regulatory licensure submissions in the autumn of 2021.

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 millions of deaths globally[4]. It has been declared a pandemic by the World Health Organization (WHO).

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

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[1] *Valneva Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001*
[2] *Valneva in Advanced Discussions with European Commission to Supply up to 60 Million Doses of Inactivated, Adjuvanted COVID-19 Vaccine Candidate*
[3] *Valneva Announces Major COVID-19 Vaccine Partnership with U.K. Government*
[4] *https://www.worldometers.info/coronavirus/*

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. The manufacturing process for VLA2001, which has already been upscaled to final industrial scale, includes inactivation with BPL to preserve the native structure of the S-protein. VLA2001 is expected to conform with standard cold chain requirements (2 degrees 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. We take a highly specialized and targeted approach to vaccine development, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. We then apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, as well as our established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. We have leveraged our 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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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, results and completion of research, development and clinical trials for product candidates, timing and volume expectations with respect to the manufacture of our product candidates; the ability to 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 sustained 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. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. 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.