

Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001

Saint Herblain (France), March 1, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the National Health Regulatory Authority (NHRA) of the Kingdom of Bahrain has granted emergency use authorization for Valneva’s inactivated, adjuvanted COVID-19 vaccine, VLA2001. This authorization follows a rolling review process with the Bahraini NHRA and reflects the NHRA’s initiative to support the authorization of COVID-19 vaccines.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, “We are extremely pleased with this first authorization and would like to thank the Kingdom of Bahrain for their trust and confidence. We are looking forward to addressing the evolution of the pandemic in the Middle East and starting to deliver our first vaccines in the region. As the only dual-adjuvanted, inactivated COVID-19 vaccine approved in Bahrain, VLA2001 will provide a differentiated vaccine option to the Bahraini population and medical community.”

Valneva signed an advance purchase agreement with the Kingdom of Bahrain in December 2021 for the supply of one million doses of VLA2001. The Company expects to deliver the first shipments of VLA2001 to Bahrain at the end of this month.

Valneva remains focused on achieving additional regulatory approvals of VLA2001. On February 25, 2022, the Company announced that it had received an initial assessment of VLA2001 from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA).¹ Based on this assessment, and subject to the CHMP’s acceptance of Valneva’s responses to a list of questions and to the timetable to be proposed by the EMA, Valneva anticipates receiving a positive CHMP recommendation for conditional approval of VLA2001 in Europe for primary immunization in adults aged 18-55 at the end of the first quarter of 2022.

About VLA2001

VLA2001 is currently the only whole virus, inactivated, adjuvanted COVID-19 vaccine in clinical development in Europe. It is intended for active immunization of at-risk populations to prevent carriage and symptomatic infection with COVID-19 during the pandemic and for routine vaccination including addressing new variants. Further, VLA2001 could potentially 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

¹ [Valneva Receives Initial CHMP Assessment of its Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001](#)



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, production 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 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.

