VALNEVA SE
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Valneva Receives Notice of European Commission's Intent to Terminate COVID-19 Vaccine Purchase Agreement

Saint-Herblain (France), May 16, 2022 – Valneva SE, a specialty vaccine company, today announced that it has received a notice from the European Commission ("EC") of intent to terminate the advance purchase agreement ("APA") for Valneva's inactivated whole-virus COVID-19 vaccine candidate VLA2001.

The APA provides the EC with a right to terminate the APA if VLA2001 had not received a marketing authorization from the European Medicines Agency ("EMA") by April 30, 2022. Based on the terms of the APA, Valneva has 30 days from May 13, 2022 to obtain a marketing authorization or propose an acceptable remediation plan.

The Company will work with the EC and the participating EC member states to agree to a remediation plan and to make VLA2001 available to those member states who still wish to receive it.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "the EC decision is regrettable especially as we continue to receive messages from Europeans who are looking for a more traditional vaccine solution. We have started a dialogue with member states who are interested in our inactivated approach. Valneva continues to believe that its vaccine candidate VLA2001 can make an important contribution to the fight against COVID-19 and complement existing vaccines with an inactivated, whole virus approach".

The Company announced on April 25, 2022[1] that it received a further List of Questions ("LoQ") from the Committee for Medicinal Products for Human Use ("CHMP") of the EMA. Valneva submitted its responses on May 2, 2022 and believes that they adequately address the remaining questions. If the CHMP accepts Valneva's responses, the Company would expect to receive a positive CHMP opinion at the latest in June 2022.

VLA2001 received a Conditional Marketing Authorization from the Medicines and Healthcare products Regulatory Agency in the United Kingdom on April 14, 2022[2] and Emergency Use Authorizations from the Ministry of Health & Prevention of the United Arab Emirates and from the National Health Regulatory Authority in Bahrain on May 13, 2022 and on February 28, 2022[3], respectively.

If the EC ultimately terminates the APA, Valneva will not be required to return the down payments received since Valneva has committed the full amount of those down payments and the APA does not require reimbursement of such payments under these circumstances.

Based on the outcome of the discussions with the EC and the relevant member states, Valneva will reconsider its full-year 2022 financial guidance.

The Company will hold an analyst call and a webcast at 3:00pm CEST or 9:00am EDT. The webcast details will be available on the Company's website.

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[1] *Valneva Provides Regulatory Update on its inactivated COVID-19 Vaccine Candidate*
[2] *Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva*
[3] *Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva*

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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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including 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.