

Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001

VLA2001 becomes the first COVID-19 vaccine to receive a standard marketing authorization in Europe

Saint Herblain (France), June 24, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the European Commission (EC) has granted marketing authorization in Europe for Valneva’s inactivated whole-virus COVID-19 vaccine, VLA2001, for use as primary vaccination in people from 18 to 50 years of age.

With this approval, VLA2001 becomes the first COVID-19 vaccine to receive a standard marketing authorization in Europe. The marketing authorization will cover all 28 European Union Member States as well as Iceland, Liechtenstein, and Norway.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, “We are extremely pleased that the EC granted full marketing authorization for VLA2001, the only inactivated whole-virus COVID-19 vaccine available in Europe. Once again, we have shown that Valneva has the expertise to bring a vaccine all the way from bench to market. Since we began working on VLA2001, we have continued to receive messages from Europeans who are waiting for a more traditional vaccine technology. Now that we have received this full marketing authorization, we hope that the EC and its member states will place orders that reflect this demand. 15% of Europeans over 18 are not yet vaccinated¹, and we believe that making our inactivated vaccine available could increase vaccination coverage and have a meaningful impact on public health.”

The EC’s approval follows recommendations yesterday from the European Medicine Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) to grant marketing authorization. This new marketing authorization in Europe follows conditional marketing authorization in the United Kingdom, which was granted in April 2022², and emergency use authorization granted in the United Arab Emirates and Bahrain in May 2022 and March 2022, respectively.

About VLA2001

VLA2001 is the only whole virus, inactivated, adjuvanted COVID-19 vaccine which has received marketing authorization in Europe for use as primary vaccination in people from 18 to 50 years of age. 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

¹ EMA Press Briefing May 5, 2022: <https://www.youtube.com/watch?v=C5DL66-Fb0Q>

² [Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva](#)



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.

