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Valneva Receives Positive CHMP Opinion for Marketing Authorization of its Inactivated COVID-19 Vaccine Candidate in Europe

Saint Herblain (France), June 23, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended marketing authorization in Europe for Valneva's inactivated whole-virus COVID-19 vaccine candidate, VLA2001, for use as primary vaccination in people from 18 to 50 years of age.

The European Commission (EC) will review the CHMP recommendation, and a decision on the marketing authorization application for VLA2001 is expected shortly. If granted, this will be the first COVID-19 vaccine to receive a standard marketing authorization in Europe.

The CHMP concluded by consensus after a thorough evaluation that, "the data on the vaccine were robust and met the EU criteria for efficacy, safety and quality."

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "We are pleased that the CHMP has recommended VLA2001, the only inactivated COVID-19 vaccine candidate in Europe, for full marketing authorization and are now looking forward to receiving marketing authorization from the EC. I would like to personally thank all those who have supported us in this endeavor, as well as everyone at Valneva for all their hard work. We hope that the EC and its member states will recognize the potential advantages of an inactivated vaccine and make a meaningful order, since we have clear evidence that Europeans are seeking a more traditional vaccine technology. Our aim is to further support public health in Europe by providing a new option for the 15% of Europeans over 18 who are not yet vaccinated[1]."

Once granted by the EC, the marketing authorization would be valid in all European Union Member States as well as in Iceland, Liechtenstein, and Norway.

The EMA's CHMP opinion follows conditional marketing authorization in the United Kingdom, which was granted in April 2022[2], and emergency use authorization granted in the United Arab Emirates in May 2022 and in Bahrain in March 2022.

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[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*

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 pandemic and 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 topossible 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.