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Valneva Confirms WHO Recommendations for its Inactivated COVID-19 Vaccine

Saint-Herblain (France), August 23, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, confirms today that the World Health Organization (WHO) has issued recommendations for use of the Company's inactivated COVID-19 vaccine.

WHO's interim recommendations for use of the Valneva VLA2001 vaccine were developed on the basis of advice issued by the Strategic Advisory Group of Experts on Immunization (SAGE) on its August 11, 2022 extraordinary meeting and published in its background document.[1]

WHO's interim recommendations also include a recommendation for a booster dose of VLA2001 four to six months after completion of the primary series and note that a booster dose of VLA2001 following primary vaccination with ChAdOx1-S (AstraZeneca) can be considered.

WHO may further update its interim recommendations to include additional uses of Valneva's COVID-19 vaccine as new data are made available.

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva, commented, "We are pleased that WHO has issued guidance on the use of Valneva's inactivated COVID-19 vaccine and believe that this guidance may support others in evaluating the potential of our vaccine to make a meaningful impact on public health. We look forward to working with WHO as they review VLA2001 for prequalification and to continuing our existing discussions with governments who are considering VLA2001 for their vaccine portfolios."

Valneva currently has agreements to supply VLA2001 to certain EU Member States[2] and the Kingdom of Bahrain[3]. Valneva is retaining inventory for potential additional supply to these EU Member States should demand increase. In parallel, the Company is continuing discussions with various other governments around the world, with the aim to deploy approximately eight to ten million doses of remaining inventory into international markets in the next six to twelve months. In light of current order levels and existing inventories, Valneva has suspended manufacturing of the vaccine.[4]

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 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

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[1] *The full interim recommendations are available here: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Valneva-VLA2001.*
[2] *European Commission Approves Purchase Agreement Amendment for Valneva's Inactivated COVID-19 Vaccine*
[3] *Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001*
[4] *European Commission Approves Purchase Agreement Amendment for Valneva's Inactivated COVID-19 Vaccine*

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).
VLA2001 is the first COVID-19 vaccine to receive a standard marketing authorization in Europe[5]. The vaccine was also granted conditional marketing authorization in the United Kingdom[6] and emergency use authorization in the United Arab Emirates[7] and Kingdom of Bahrain[8].

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 purchase agreements and regulatory approval of VLA2001 and clinical trial results. 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 in this press release 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.

[5] *Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001*
[6] *Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine*
[7] *Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine*
[8] *Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001*