

European Commission Approves Purchase Agreement Amendment for Valneva's Inactivated COVID-19 Vaccine

European Commission to order 1.25 million doses of Valneva's whole-virus COVID-19 vaccine VLA2001 in 2022

Saint-Herblain (France), July 20, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announces that the European Commission (EC) has approved an amendment to the Advance Purchase Agreement (APA) it signed in November 2021¹ for Valneva's inactivated whole-virus COVID-19 vaccine, VLA2001. The amendment will be signed after a mandatory five-day period during which Member States can opt out. Under this amendment, the Member States' purchases will consist of 1.25 million doses of VLA2001 in 2022, with the option to purchase an equivalent quantity later this year for delivery in 2022. This amendment follows remediation discussions based on the EC's notice of intent² to terminate the initial APA for VLA2001 doses in 2022 and optional doses for 2023.

The first vaccine doses will be delivered to participating EU Member States (Germany, Austria, Denmark, Finland and Bulgaria) in the coming weeks. Valneva will retain inventory for potential additional supply to these EU Member States should demand increase and, in parallel, will aim to deploy approximately eight to ten million doses of remaining inventory into international markets. Given that VLA2001's shelf life is expected to reach up to 24 months over time, the Company will aim to deploy these doses in the next six to twelve months.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "We welcome the fact that the EC has decided not to terminate the APA, although we feel the order volume does not reflect the interest we see from European citizens. Despite this, we have decided to enter into this amendment to make our vaccine available to the Europeans who have been waiting for it. While the pandemic had been declining, the latest COVID-19 wave in Europe clearly underlines the need for alternative vaccines. 15% of Europeans over 18 are not yet vaccinated³ and we continue to receive messages from Europeans who are awaiting a more traditional vaccine technology. Recent market studies⁴ conducted in several EU member states suggest that making our inactivated vaccine available in Europe could increase vaccine uptake and have a meaningful impact on public health."

In light of the reduced order volume from EU member states, the Company is evaluating the COVID-19 program and associated operations. Valneva continues discussions on potential additional supply and financing agreements with various other countries around the world and will invest in further development of its current or second-generation COVID-19 vaccine only if it reaches an agreement with potential customers and receives the necessary funding over the summer.

¹ [Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001](#)

² [Valneva Receives Notice of European Commission's Intent to Terminate COVID-19 Vaccine Purchase Agreement – Valneva](#)

³ [EMA Press Briefing May 5, 2022: <https://www.youtube.com/watch?v=C5DL66-Fb0Q>](#)

⁴ https://www.ipsos.com/sites/default/files/ct/news/documents/2022-06/ipsos-PI_Inaktivierter-Impfstoff-Valneva_2022-06-29.pdf; <https://www.ipsos.com/fr-fr/covid-19-lutilisation-dun-vaccin-inactive-en-france-augmenterait-la-couverture-vaccinale>



Valneva does not expect immediate cash constraints following this change in the EC order and believes that its 2022 revenues could still reach the lower end of its previously communicated guidance⁵ based on revenue recognition linked to the EC and UK supply contracts. In light of the amended APA, Valneva has suspended manufacturing of VLA2001 and is assessing its COVID-19 related assets with regard to any potential write-down. The Company will provide a more detailed update on its plans and financial guidance with its first half results on August 11, 2022.

In parallel, Valneva will continue to progress its two late-stage assets: its Lyme disease vaccine candidate, which is partnered with Pfizer and expected to enter its Phase 3 study in the third quarter of 2022, and its single-shot chikungunya vaccine candidate for which the Company expects to commence submission of the Biologics License Application with the US FDA in the second half of 2022. Valneva is also actively working to add new vaccine candidates to its clinical pipeline, both through the advancement of its preclinical assets and potential program acquisitions.

VLA2001 is the first COVID-19 vaccine to receive a standard marketing authorization in Europe⁶. The vaccine was also granted conditional marketing authorization in the United Kingdom⁷ and emergency use authorization in the United Arab Emirates⁸ and Kingdom of Bahrain⁹.

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 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

⁵ [Valneva Reports Q1 2022 Results and Provides Corporate Updates - Valneva](#)

⁶ [Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001](#)

⁷ [Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva](#)

⁸ [Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine](#)

⁹ [Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva](#)



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.

Media & Investor Contacts

Laëtitia Bachelot-Fontaine
VP Global Communications & European Investor Relations
M +33 (0)6 4516 7099
laetitia.bachelot-fontaine@valneva.com

Joshua Drumm, Ph.D.
VP Global Investor Relations
M +001 917 815 4520
joshua.drumm@valneva.com

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, timing and plans for clinical programs and product candidates and revenue forecasts. 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.

