VALNEVA SE
Campus Bio-Ouest | 6, Rue Alain Bombard
44800 Saint-Herblain, *France*

Valneva Provides Regulatory Update on its inactivated COVID-19 Vaccine Candidate

Saint Herblain (France), April 25, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today provided an update on the rolling review process of its inactivated, COVID-19 vaccine candidate, VLA2001, with the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA").

Following last week's meeting, the CHMP provided another List of Questions ("LoQ"). This LoQ includes requests for additional data and for further justification of a Conditional Marketing Authorization.

Valneva will respond to these requests in the coming days. If the CHMP accepts the submissions, the Company would expect a Conditional Marketing Authorization this quarter.

Valneva continues to believe that its inactivated vaccine meets the conditions for a Conditional Marketing Authorization, including a positive benefit-risk profile. The Company remains focused on achieving a Conditional Marketing Authorization for VLA2001 in Europe after it was granted Conditional Marketing Authorization by the Medicines and Healthcare products Regulatory Agency ("MHRA") of the United Kingdom ("UK") two weeks ago[1].

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "We are disappointed that the EMA has not considered our submissions sufficient to date. We remain fully committed and dedicated to working jointly with the regulators towards a product approval. VLA2001 is the only inactivated COVID-19 vaccine candidate in Europe, and we continue to receive messages every day from people who are looking for a more traditional vaccine approach".

In its Phase 3 pivotal trial, Valneva demonstrated that two doses of VLA2001 induced superior neutralizing antibody levels and a significantly better tolerability profile compared to another EMA-approved vaccine (AZD1222)[2]. On April 14, 2022, the UK MHRA granted Conditional Marketing Authorization for VLA2001 for primary immunization in adults 18 to 50 years of age[3]. MHRA found that VLA2001 meets the required safety, quality and effectiveness standards. This authorization followed emergency use authorization from the Bahraini NHRA in March 2022[4].

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

[1] *Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva*
[2] *Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001 – Valneva*
[3] *Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva*
[4] *Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva*

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.

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 the progress, timing, design, data read-outs, anticipated results and completion of clinical trials of VLA2001 and 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.