

Valneva Publishes Amendment to 2020 Universal Registration Document

Saint Herblain (France), October 27, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced the publication of an amendment filed with the French Financial Markets Authority (“AMF”) on October 26, 2021 under the filing number D.21-0286-A01 (the “URD Amendment”) to its 2020 Universal Registration Document (“URD”), filed with the AMF on April 9, 2021 under the filing number D.21-0286. The key amendments made to the URD, including certain information updates, are discussed below.

In October 2021, the Company announced positive Phase 3 initial results for VLA2001, a highly purified, inactivated and adjuvanted vaccine candidate against the SARS-CoV-2 virus that causes COVID-19.¹ In anticipation of these results, the Company commenced its rolling submission and review process with the UK’s Medicines & Healthcare products Regulatory Agency (“MHRA”), in August 2021.² The Company expects to incorporate its positive Phase 3 initial results into this submission in November 2021 and believes that it could receive MHRA approval by the end of 2021. The Company is also preparing to commence a rolling review process with the European Medicines Agency, (“EMA”). Further submissions to other regulatory agencies may take place in 2022.

In September 2021, Valneva and Pfizer Inc. announced positive new Phase 2 results, including data after a booster dose, for Valneva’s Lyme disease vaccine candidate, VLA15.³ The two companies are working closely together on the next development steps and are planning for a placebo-controlled pivotal Phase 3 trial in 2022. The dosing of the first subject in the Phase 3 clinical trial will trigger a milestone payment from Pfizer of \$25 million.

In relation to VLA1553, the Company’s chikungunya vaccine candidate, the Company has received confirmation from the EMA of its acceptance of the surrogate of protection Valneva had previously agreed with the US Food & Drug Administration (“FDA”) to use as a base for licensure of VLA1553. The Company announced in August 2021 that the seroprotection rate observed in the pivotal Phase 3 trial of VLA1553 was 98.5%, exceeding the 70% surrogate of protection threshold agreed with the FDA.⁴

The URD Amendment includes an explanation of i) changes to the Company’s segment reporting structure effective as of January 1, 2021 and ii) events after the reporting period, which describes the circumstances of the termination of the agreement to supply VLA2001, the

¹ [Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001](#)

² [Valneva Commences Rolling Submission to MHRA for its Inactivated, Adjuvanted COVID-19 Vaccine](#)

³ [Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate](#)

⁴ [Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate](#)

Company's COVID-19 vaccine candidate, to the United Kingdom (the "UK Supply Agreement")⁵ and the potential impact of this termination.

The URD Amendment explains that the UK government (the "UK Authority") provided notice of its decision to terminate the UK Supply Agreement following the close of business on September 10, 2021. This included an allegation that Valneva would be in future breach of the UK Supply Agreement which claim could give rise to a liability for damages (the contractual cap on which would not exceed the amounts received). As detailed in the URD Amendment, Valneva strongly disputes any claims relating to breach of the UK Supply Agreement (and believes that it is very unlikely that any such claim by the UK Authority would ultimately be successful) but has acknowledged termination of the UK Supply Agreement for convenience by the UK Authority effective as of October 10, 2021 (and associated obligations on the part of Valneva and the UK Authority arising from or surviving termination of the Agreement). Valneva is not obligated to refund or repay any amount paid by the UK Authority in case of termination for convenience. Further details are available in the URD Amendment.

Valneva is continuing to discuss the final terms of the termination of the UK Supply Agreement with the UK Authority, and those final terms as well as other commercial opportunities and receipt of regulatory approval of VLA2001 may impact the Company's financial position. The potential impact of the termination of the UK Supply Agreement on the Company's financial position is presented in the note on events after the reporting period included in the URD Amendment. The note discusses potential impact on the Company's inventories and advance payments for inventories, property, plant and equipment, refund liabilities, and contract liabilities.

Additionally, the Company has received a request for information from a directorate within Health Canada, the agency supervising pharmaceutical products in Canada, regarding the data supporting the indication and labeling of the Company's product DUKORAL[®]. This remains an ongoing matter, and if the indications or labeling of DUKORAL[®] were to change significantly in Canada, this could have a significant negative impact on the Company's sales which could in turn result in the product no longer being economically viable.

Finally, the Company had planned to communicate its third quarter results on November 18, 2021. Given the difficulty of assessing the impact of a number of post-closing events at this time, the Company will communicate, on November 18, 2021, only its cash position for the quarter ended September 30, 2021 and its revenues for the nine months ended September 30, 2021. The year-end closing on December 31, 2021 will allow for the integration of all necessary elements.

The URD Amendment is available on the Company's corporate website (<https://valneva.com/investors/financial-reports/>) and on the AMF's website (www.amf-france.org) and should be read together with the URD. A hard copy of the document may be obtained from the Company, free of charge and upon request, at the following address: 6 rue Alain Bombard, 44800 Saint-Herblain, France.

⁵ [*Valneva Receives Notice of Termination of COVID-19 Vaccine Supply Agreement by UK Government*](#)



Valneva has publicly filed a registration statement on Form F-1 with the Securities and Exchange Commission (SEC) in the United States. This document refers to a potential public offering of American Depositary Shares in the United States and a concurrent private placement of ordinary shares in Europe (together, the “Global Offering”), and discloses the potential use of proceeds in the event of the completion of such offering.

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 & Investors Contacts

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

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

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the potential consequences of termination of the UK Supply Agreement, relating to the progress, timing, results and completion of research, development and clinical trials for product candidates, to regulatory approval of product candidates and review of existing products, and to estimates for future performance. 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 sustained in the future. 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 largely 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, and the ability to obtain or maintain patent or other proprietary intellectual property protection. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. 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 these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

