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# Valneva Receives Notice of Termination of COVID-19 Vaccine Supply Agreement by UK Government

Saint-Herblain (France), September 13, 2021 – <u>Valneva SE</u>, a specialty vaccine company, today announced that it has received a termination notice from the UK Government ("HMG") in relation to the Supply Agreement for its COVID-19 vaccine candidate, VLA2001. The contract provides HMG with the right to terminate. HMG has alleged that the Company is in breach of its obligations under the Supply Agreement, but the Company strenuously denies this.

Valneva is continuing its VLA2001 development plan. Testing for the Company's pivotal Phase 3 trial, Cov-Compare, is ongoing at Public Health England ("PHE"). Valneva recently announced that its Phase 3 results are expected to be available early in the fourth quarter and that these results will form part of its rolling submission for conditional approval of VLA2001 with the UK's Medicines and Healthcare products Regulatory Agency ("MHRA"). Subject to these data and MHRA approval, Valneva believes that initial approval for VLA2001 could be granted in late 2021.

Valneva has worked tirelessly, and to its best efforts, on the collaboration with HMG including investing significant resources and effort to respond to HMG's requests for variant-derived vaccines. Valneva continues to be committed to the development of VLA2001 and will increase its efforts with other potential customers to ensure that its inactivated vaccine can be used in the fight against the pandemic.

### **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 ongoing pandemic and potentially later 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, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. It then applies its deep understanding of vaccine science, including its expertise across multiple vaccine modalities, as well as its



established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. The Company 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, COVID-19 and the chikungunya virus.

#### **Media & Investor Contacts**

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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 the progress, timing, design, data read-outs, anticipated results and completion of clinical trials for 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 forwardlooking 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, the cancellation of existing contracts, including but not limited to the HMG Supply Agreement, and the impact of the COVID-19 pandemic, the occurrence of any of which could substantially harm Valneva's business, financial condition, prospects and results of operations. 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.