

## Valneva to Participate in the World's First COVID-19 Vaccine Booster Trial in the UK

**Saint-Herblain (France), May 19, 2021** – Valneva SE, a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, today announced it will participate in a UK government-funded clinical trial looking at different COVID-19 'booster' vaccines that launches today.

The Cov-Boost trial, led by University Hospital Southampton NHS Foundation Trust, will look at seven different COVID-19 vaccines, including Valneva's inactivated vaccine VLA2001, as potential boosters. It will be the first trial in the world to provide vital data on how effective a booster of each vaccine is in protecting individuals from the virus.

The vaccines will be given at least three months after a second dose as part of the ongoing vaccination programme. One booster will be provided to each volunteer and could be a different brand to the one they were originally vaccinated with. The trial will also include a control group.

Initial results from the trial, expected in September, will help inform decisions by the UK Joint Committee on Vaccination and Immunisation (JCVI) on any potential booster programme from autumn this year, ensuring the UK's most vulnerable people are given the strongest possible protection over the winter period.

**Thomas Lingelbach, Chief Executive Officer of Valneva**, commented, *"We are pleased to be involved in this new Cov-Boost trial. Valneva has the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 in Europe and we believe our VLA2001 vaccine has an important role to play in the ongoing pandemic, including as a booster. We remain fully committed to completing development and bringing our inactivated vaccine solution to the market."*

In parallel to the Cov-Boost trial, Valneva will continue working on its pivotal Phase 3 clinical trial "Cov-Compare", (VLA2001-301) which the Company launched in April 2021<sup>1</sup>. This trial compares Valneva's SARS-CoV-2 vaccine candidate, VLA2001, against AstraZeneca's conditionally approved vaccine, Vaxzevria<sup>2</sup>. Recruitment for the trial, conducted in the U.K. and supported by the National Institute for Health Research (NIHR), is ongoing (<https://www.ukcovid19study.com/>). Subject to successful Phase 3 data, Valneva aims to make regulatory submissions for initial approval in the autumn of 2021.

### 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

<sup>1</sup> Valneva Initiates Phase 3 Clinical Trial for its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001

<sup>2</sup> Approved by MHRA under reg. 174 and by the European Commission as conditional approval



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. The manufacturing process for VLA2001, which has already been upscaled to final industrial scale, includes inactivation with BPL to preserve the native structure of the S-protein. VLA2001 is expected to conform with standard cold chain requirements (2 degrees 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. We take 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. We then apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, as well as our established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. We have leveraged our 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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This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing, results and completion of research, development and clinical trials for product candidates and 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.