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Valneva Completes Recruitment of Elderly Participants in Phase 3 Trial of its Inactivated COVID-19 Vaccine

Saint-Herblain (France), September 14, 2021 – Valneva SE, a specialty vaccine company, today announced that it has completed recruitment of the initial cohort of elderly participants in Valneva's Phase 3 trial, VLA2001-304, of its inactivated COVID-19 vaccine candidate, VLA2001.

300 volunteers aged 56 years and older have been recruited in New Zealand into the VLA2001-304 trial with the objective to generate further safety and immunogenicity data for this age group. The cohort size has been increased to 300, from 150, in consultation with the European Medicines Agency ("EMA"). Topline data from this cohort will read out in early 2022, and it is expected that the data will support additional regulatory submissions.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "We initiated this trial approximately a month ago, so we are extremely pleased to achieve this important milestone in such a short period of time. We believe that our differentiated vaccine candidate can make a major contribution to the ongoing fight against the COVID-19 pandemic."

VLA2001 is currently the only inactivated vaccine candidate in clinical trials against COVID-19 in Europe. In parallel to the VLA2001-304 trial in New Zealand, VLA2001 is currently being studied in the United Kingdom (UK) in a pivotal Phase 3 trial, "Cov-Compare" (VLA2001-301), for which top-line results are currently expected early in the fourth quarter 2021. Valneva has commenced rolling submission for conditional approval with the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

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 VLA2001-304

Trial VLA2001-304 is expected to enroll two cohorts. Cohort 1 includes 300 volunteers aged 56 years and older in an open-label manner in order to generate safety and immunogenicity data for VLA2001 in this age group. Cohort 2 of the trial is expected to include approximately 600 volunteers aged 12 years and older in order to compare immunogenicity data of Valneva's original COVID-19

vaccine candidate, VLA2001, to an additional COVID-19 vaccine candidate, VLA2101, based on a variant strain to be confirmed. In both cohorts, vaccinations will be administered in a two-dose immunization schedule 28 days apart. The trial will be conducted at approximately 10 trial sites in New Zealand. ClinicalTrials.gov Identifier: NCT04956224

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.

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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 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.