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Valneva Comments on COV-Boost Clinical Trial Data

Saint Herblain (France), December 3, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today responded to data published from the COV-Boost COVID-19 vaccine trial, which investigated the reactogenicity and immunogenicity of seven different COVID-19 vaccines at different dose levels when administered as a third dose, or booster, to people primed with either Pfizer's Comirnaty or AstraZeneca's Vaxzevria.

The COV-Boost trial, which launched in May 2021 and was led by University Hospital Southampton NHS Foundation Trust, included Valneva's inactivated, adjuvanted, whole virus COVID-19 vaccine candidate VLA2001. The aim of the COV-Boost trial was to quickly generate data to inform advice from the UK's Joint Committee on Vaccination and Immunization on the autumn booster campaign. Participants were given a booster dose relatively early, only two to three months after completion of the second dose of the primary vaccination series, when they did not need a booster from either an immunological standpoint or under the currently recommended interval for licensed COVID-19 vaccines. Valneva believes it is likely that the short interval between the second shot and booster shot could have adversely impacted the results for VLA2001, given that a longer interval is generally required for inactivated vaccines.

The Company has already begun generating data to inform any regulatory discussions regarding a potential booster indication for VLA2001. The first data from a continuation of existing clinical trials (homologous) are expected in the first quarter of 2022. Additionally, Valneva is in the process of setting up a dedicated heterologous booster trial. All of Valneva's trials will evaluate a booster shot provided at least six months after primary vaccination, as per the currently recommended interval for licensed COVID-19 vaccines. The results of the COV-Boost trial were never intended to be, nor will they be, part of the Company's regulatory submissions to the UK Medicines and Healthcare products Regulatory Agency (MHRA) and European Medicines Agency (EMA), which seek approvals for VLA2001 in the primary vaccination context solely based on the positive data from the pivotal Phase 3 Cov-Compare trial.

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva, said, "The setting in the study leads us to believe that COV-Boost does not allow any conclusions to be reached regarding the use of VLA2001 as a booster in a real-life setting. The protective antibody threshold has not yet been established therefore relative increases in antibody levels should not be seen as indicative of efficacy. I concur with Professor Faust's statements that the data describe the immune response at 28 days, not vaccine effectiveness, and that the relationship between that response and long-term protection is still poorly understood, especially since several studies have shown that longer periods between doses improve immune response. Our submissions for authorization of VLA2001 in a primary vaccination context remain on track, with the EMA announcing yesterday that it has started its rolling review of VLA2001, and our teams are working diligently so that we can quickly deploy our vaccine and ensure it reaches the people who need it."

On October 18, 2021, Valneva announced positive topline results from Cov-Compare, the pivotal Phase 3 comparative immunogenicity trial of VLA2001. VLA2001 demonstrated superiority in terms of neutralizing antibody titer levels against the active comparator vaccine, AstraZeneca's AZD1222, as well as non-inferiority in terms of seroconversion rates and a significantly better tolerability profile. The Company commenced rolling submission for initial approval of VLA2001 with the MHRA on August 23, 2021 and rolling review with the EMA on December 2 and will continue to work very closely with those authorities to complete their review process.

Valneva announced on November 23, 2021 that the European Commission signed an agreement for the Company to supply up to 60 million doses of VLA2001 over two years - including 24.3 million doses in 2022. Delivery of the vaccine is currently expected to begin in April 2022, subject to approval by the EMA.

About VLA2001

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate against COVID-19 in clinical trials 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. The manufacturing process for VLA2001, 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 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. 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.

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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 and regulatory review processes 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, 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.