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Valneva Confirms Initiation of Rolling Review with EMA and Provides Updates on its COVID-19 Vaccine Program VLA2001

Saint-Herblain (France), December 2, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today confirmed that the European Medicines Agency (EMA) has started a rolling review of VLA2001, its whole-virus inactivated, adjuvanted COVID-19 vaccine candidate.

Valneva remains focused on achieving regulatory approvals of VLA2001 following its positive Phase 3 trial results. The Company continues to make progress with the rolling submission in the UK (MHRA), including verification of the Phase 3 clinical data integrity (required for finalization of the submission), as previously disclosed. Potential regulatory approvals are expected in the first quarter of 2022.

Valneva is also providing an update on VLA2001 in the context of the emergence of the Omicron variant. Valneva believes that VLA2001 can make an important contribution to the global fight against the COVID-19 pandemic and potentially play a role in protecting against the new Omicron variant.

In contrast to other vaccines that target only the spike protein of the SARS-COV-2 virus, VLA2001 is developed using the entire SARS-CoV-2 virus envelope. Preserving the whole virus envelope is expected to elicit a broad immune response and together with the CpG1018 adjuvant may provide an improved immunological profile by boosting T-cell responses against additional SARS-CoV-2 proteins. Valneva will test for cross-neutralization of VLA2001 against the Omicron variant.

Valneva also confirms that its technology platform is adaptable for new variants, if required. The Company has undertaken laboratory development and testing of variants, at its sites in France and Austria, including the production of viral seed stock for three earlier variants of concern, including Delta. Valneva produced a full scale pilot lot derived from the Alpha variant, validating the suitability of its well-established manufacturing process for variant-based vaccines.

Valneva has commenced manufacturing for the European Commission supply contract and has some inventory ready for labelling and deployment upon regulatory approval. Valneva expects to have capacity to produce over a hundred million doses of vaccine per annum through a combination of in house production and CMO capacity.

Commenting, Thomas Lingelbach, Chief Executive Officer of Valneva, said, “The latest COVID-19 wave in Europe underlines the need for additional vaccines and we continue to believe that VLA2001 will contribute to addressing the pandemic. We are hopeful that our vaccine candidate might cross protect against variants to the SARS-CoV-2 virus and also have the flexibility, knowledge and resources to adapt if required. Our teams are working diligently to achieve regulatory submissions so that we can quickly deploy our vaccine and ensure that it reaches people who need it.”

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.