

Valneva and IDT Biologika Announce Collaboration for Production of Inactivated COVID-19 Vaccine VLA2001

Saint-Herblain (France) and Dessau-Roßlau (Germany), November 29, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and IDT Biologika today announced their collaboration for the production of Valneva’s inactivated COVID-19 vaccine candidate VLA2001. This follows last week’s announcement that Valneva signed an Advance Purchase Agreement with the European Commission to supply up to 60 million doses of VLA2001, over two years.

Under the collaboration, IDT Biologika will produce VLA2001’s drug substance at its Biosafety Level 3 facilities in Dessau-Roßlau, Germany, in addition to Valneva’s manufacturing site in Livingston, Scotland.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, “IDT is a well-established partner within Valneva’s manufacturing network. As such we are extremely pleased to extend this partnership to supply VLA2001. This collaboration will help ensure our inactivated vaccine is available for rapid deployment as we continue to believe that our differentiated vaccine candidate can make an important contribution to the global fight against the COVID-19 pandemic.”

Dr. Jürgen Betzing, Chief Executive Officer of IDT Biologika, added, “This is great news for our company. This assignment shows the importance of the role played by IDT in the fight against COVID-19. It is a great achievement and demonstrates the trust that Valneva has placed in us and our employees. The expansion of our production capacity combined with our expertise were key factors in the choice of IDT.”

Valneva has continued to review its manufacturing strategy following discussions with the UK Government (“HMG”) in the summer and again after the termination of the UK contract in September 2021. Valneva plans to operate a combination of external and internal production of VLA2001 and will further review its manufacturing plans based on demand. The Company’s sites in Livingston, Scotland and Solna, Sweden will continue to form part of the Company’s core manufacturing strategy.

Valneva reported positive Phase 3 results for VLA2001 in October 2021¹. Delivery of the vaccine in Europe is currently expected to begin in April 2022, subject to approval by the European Medicines Agency (EMA), which is expected to start a rolling review of VLA2001 shortly.

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

¹ [Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001](#)





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.

About IDT Biologika

IDT Biologika is an innovative biotech company with a successful history dating back 100 years. On the basis of modern technologies and high levels of expertise, we support customers in the development and manufacture of innovative virus vaccines, gene and immune therapy products as well as biologics employed worldwide as protection against diseases. German sites are the BioPharmaPark in Dessau-Roßlau and Magdeburg. In the US, the IDT Corporation has a manufacturing site for clinical test samples in Rockville, Maryland.

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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.

