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Valneva Announces Publication of its COVID-19 Vaccine Phase 3 Data in *The Lancet Infectious Diseases*

Saint-Herblain (France), September 6, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announces that *The Lancet Infectious Diseases ("The Lancet ID")*, a peer-reviewed medical journal, has published the Company's pivotal Phase 3 clinical data for its inactivated, whole-virus COVID-19 vaccine, VLA2001.

The paper, entitled "Immunogenicity and safety of an inactivated whole-virus COVID-19 vaccine (VLA2001) compared with the adenoviral vector vaccine ChAdOx1 in adults in the UK (COV-COMPARE): interim analysis of a randomised, controlled, phase 3, immunobridging trial" provides a detailed analysis of the Phase 3 results, showing that VLA2001 demonstrated superior neutralizing antibody titer levels versus the comparator vaccine, as well as broad T-cell responses against the S- (spike), M- (membrane), and N- (neucleocapsid) proteins, and a significantly better tolerability profile versus the comparator vaccine. It can be accessed via the following link: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00502-3/fulltext.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "This Lancet publication is a strong scientific and developmental validation of the work that has been accomplished at Valneva. We are pleased that more detailed results on our inactivated COVID-19 vaccine are now available to the scientific and broader public health communities."

Valneva reported positive topline Phase 3 results for VLA2001 in October 2021[1].

In August 2022, the World Health Organization issued recommendations for use of Valneva's inactivated COVID-19 vaccine[2].

The Company published safety and immunogenicity data from the Phase 1/2 trial of VLA2001 in the *Journal of Infection*[3] in June 2022.

About VLA2001

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).
VLA2001 is the first COVID-19 vaccine to receive a standard marketing authorization in Europe[4] and the only whole virus, inactivated, adjuvanted COVID-19 vaccine to receive marketing authorization in

[1] *Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001*
[2] *Valneva Confirms WHO Recommendations for its Inactivated COVID-19 Vaccine*
[3] *https://pubmed.ncbi.nlm.nih.gov/35718205/*
[4] *Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001*

Europe for use as primary vaccination in people from 18 to 50 years of age. The vaccine was also granted conditional marketing authorization in the United Kingdom[5] and emergency use authorization in the United Arab Emirates[6] and Kingdom of Bahrain[7]. Valneva currently has agreements to supply VLA2001 to certain EU Member States[8] and the Kingdom of Bahrain[9]. In August 2022, the World Health Organization (WHO) issued recommendations for use of VLA2001[10]. In light of current order levels and existing inventories, Valneva has suspended manufacturing of the vaccine[11]. Valneva is retaining inventory for potential additional supply to these EU Member States should demand increase. In parallel, the Company is continuing discussions with various other governments around the world, with the aim to deploy approximately eight to ten million doses of remaining inventory into international markets in the next six to twelve months.

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 commercialize three vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease and the chikungunya virus.

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[5] *Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine*
[6] *Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine*
[7] *Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001*
[8] *European Commission Approves Purchase Agreement Amendment for Valneva's Inactivated COVID-19 Vaccine*
[9] *Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001*
[10] *Valneva Confirms WHO Recommendations for its Inactivated COVID-19 Vaccine*
[11] *European Commission Approves Purchase Agreement Amendment for Valneva's Inactivated COVID-19 Vaccine*