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Valneva Announces Positive Homologous Booster Data for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001

- Initial results show excellent immune response after third dose of VLA2001 administered 7 to 8 months after the second dose of primary vaccination
- Antibody titers increased 42- to 106-fold two weeks after booster dose vs pre-booster levels
- Antibody titers four-fold higher compared to two weeks after primary immunization
- Evaluating sera from boosted participants for cross-neutralization against Variants Of Concern, including Omicron

Saint Herblain (France), December 16, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced positive homologous booster data from the Phase 1/2 study, of its inactivated, adjuvanted COVID-19 vaccine candidate, VLA2001. Initial results confirm that VLA2001 significantly boosted immunity in participants who received VLA2001 as a primary vaccination.

77 of the 153 original Phase 1/2 study participants, aged 18-55 years, received a booster dose seven to eight months after completion of their primary immunization with either a low, medium or high dose of VLA2001. All participants received a single booster vaccination with VLA2001 at the same (high) dose level used in the pivotal Phase 3 "Cov-Compare" trial.[1] IgG antibody titers (spike protein-based) were measured at the time of the booster as well as two weeks after the booster dose. 45 of the 77 boosted participants were included in the final analysis.[2]

A third dose of VLA2001 elicited an excellent anamnestic response, with similar antibody levels observed whether participants were initially vaccinated with a low, medium or high dose (GMT 9699.3 (95%CI: 8497.76, 11070.71)). This represents a strong boosting effect, increasing levels of antibodies against the Wuhan virus 42- to 106-fold, depending on the pre-boosting levels of antibodies.

Antibody levels measured two weeks after the booster dose were approximately four-fold higher compared to those observed two weeks after primary immunization.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented: "We are extremely pleased to report our first booster data, confirming that VLA2001 significantly boosted

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

[2] *27 of the remaining participants who were not included in the final analysis had also received another COVID-19 vaccine, and five experienced a COVID-19 infection during the study.*

immunity in participants who received VLA2001 as a primary vaccination and regardless of the initial neutralizing antibody level at the time of boosting. Boostering several months, typically six months or more, after primary immunisation is generally effective for inactivated, adjuvanted vaccines. Our teams are working diligently on our rolling review regulatory submissions so that we can quickly deploy our vaccine and ensure it reaches the people who need it. I would like to thank again the trial investigators, participants and collaborators, especially the National Institute for Health Research and the clinical teams within the NHS Research Centres."

In addition to these initial booster data, Valneva expects to report further homologous booster data from the Phase 3 Cov-Compare study. In parallel, the Company is preparing to launch a dedicated heterologous booster trial, which will evaluate a VLA2001 booster shot provided at least six months after primary vaccination with other vaccines or following natural infection. This study is expected to commence in early 2022.

Valneva will also evaluate the sera from the boosted participants for cross-neutralization against Variants of Concern, including Omicron.

About Phase 1/2 Trial VLA2001-201

VLA2001-201 is a randomized, dose-finding trial to evaluate the safety, tolerability and immunogenicity of the inactivated, adjuvanted SARS-CoV-2 virus vaccine candidate VLA2001 in healthy subjects. VLA2001-201 is the first-in-human Phase 1/2 trial evaluating three dose levels of VLA2001 (low, medium, high) for safety, tolerability and immunogenicity in a two-dose schedule with intra muscular vaccinations three weeks apart. Overall, 153 healthy young adults aged 18 to 55 years were recruited in the trial. VLA2001-201 is being conducted in two parts: Part A (Day 1 to Day 36) and Part B (Day 37 to Day 208).

77 subjects from the 153 study participants originally included in the Phase 1/2 trial received a booster dose approximately 7-8 months after completion of their primary vaccination series.

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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