VALNEVA SE
Campus Bio-Ouest | 6, Rue Alain Bombard
44800 Saint-Herblain, *France*

Valneva Provides Clinical and Regulatory Updates for its COVID-19 Vaccine VLA2001

Saint-Herblain (France), March 2, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced additional data from remaining clinical studies and an update on regulatory submissions for its inactivated COVID-19 vaccine, VLA2001. As previously announced, Valneva will not invest in further development of the vaccine, in the absence of a new partnership[1]. It is, however, completing remaining clinical studies and submissions as agreed with regulators.

On February 23, 2023, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion for the use of VLA2001 in adults 18 to 50 years of age as a booster dose to be given at least seven months following primary vaccination (the second dose) with VLA2001 (homologous booster dose) or with an adenoviral vector COVID-19 vaccine (heterologous booster dose).

Valneva also provided an update on its pivotal Phase 3 Study COV-Compare (VLA2001-301). In this study, neutralizing antibodies on Day 208 (six months after the second dose of the primary vaccination with VLA2001) were non-inferior compared to the active comparator AZD1222, an adenoviral vector vaccine. The fold decline of neutralizing antibodies over six months after a second vaccination with VLA2001 was similar to the active comparator, and less pronounced than for other licensed COVID-19 vaccines[2,3]. The T-cell response against the spike protein elicited upon vaccination with VLA2001 was in the same range as for the active comparator. Moreover, T-cell reactivity against the nucleocapsid and membrane protein was induced upon vaccination with VLA2001.

Additionally, results from VLA2001-304, a Phase 3 study in older adults, 56 years of age and above, showed that VLA2001 was well tolerated by these participants when administered as a two-dose or three-dose immunization, thus confirming the previously reported favorable safety profile of VLA2001[4]. In this age group, a two-dose vaccination with VLA2001 was inferior in terms of geometric mean titers and seroconversion rates compared to younger adults aged 30 years and above. After two doses, immunogenicity in older adults was at a level which could be correlated with 60-70% vaccine efficacy against ancestral SARS-CoV-2[5]. A third dose of VLA2001 further increased immunogenicity in participants aged 56 years and above to the titers associated with vaccine efficacy of >90% against ancestral SARS-CoV-2[6,7].

Finally, VLA2001's shelf life was recently extended to 21 months compared to 18 months previously. The Company will continue to submit data to further extend it.

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[1] *Valneva Reports H1 2022 Results and Provides Corporate Updates - Valneva*
[2] *Pajon R et al. N Engl J Med 2022; 386:1088-1091*
[3] *Zeng G et al. Lancet Infect Dis. 2022 Apr;22(4):483-495*
[4] *Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted Covid-19 Vaccine Candidate VLA2001 (October 18, 2021*
[5] *Valneva Reports Further Positive Phase 3 Immunogenicity and the First Heterologous Booster Results for its Inactivated, Adjuvanted COVID-19 Vaccine VLA2001 (August 29, 2022)*
[6] *S. Feng et al., Nature Medicine 10.1038/s41591-021-01540-1 (2021)*
[7] *P. B. Gilbert et al., Science 10.1126/science.abm3425 (2021)*

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 was 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 was the first COVID-19 vaccine to receive a standard marketing authorization in Europe[8] and the only whole virus, inactivated, COVID-19 vaccine to receive marketing authorization in 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[9] and emergency use authorization in the United Arab Emirates[10] and Kingdom of Bahrain[11]. Valneva signed agreements to supply VLA2001 to certain EU Member States and the Kingdom of Bahrain[12]. In August 2022, the World Health Organization (WHO) issued recommendations for use of VLA2001[13]. In light of current order levels and existing inventories, Valneva has suspended manufacturing of the vaccine and is continuing discussions on the potential sale of some of the remaining inventory. VLA2001 currently has a 21-month shelf life and the Company will continue to submit data to further extend it.

About Valneva SE

Valneva is a specialty vaccine company focused on the development, manufacturing 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 the chikungunya virus and Lyme disease.

Valneva Investor and Media Contacts

Laetitia Bachelot-Fontaine
VP Global Communications & European Investor Relations
M +33 (0)6 4516 7099
laetitia.bachelot-fontaine@valneva.com

Joshua Drumm, Ph.D.
VP Global Investor Relations
M +001 917 815 4520
joshua.drumm@valneva.com

Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing, results and completion of research,

[8] *Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001*
[9] *Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine*
[10] *Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine*
[11] *Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001*
[12] *Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001*
[13] *Valneva Confirms WHO Recommendations for its Inactivated COVID-19 Vaccine*

development and clinical trials for product candidates, to regulatory approval of product candidates and review of existing products. 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 sustained in the future. 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 largely 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 and delays 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, and the ability to obtain or maintain patent or other proprietary intellectual property protection. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. 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 these materials as of this press release and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.