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

Valneva Reports Positive Results for Phase 1 Trial of Second-Generation Zika Vaccine Candidate

Immune response successfully improved with second generation vaccine candidate

Saint-Herblain (France), November 4, 2025 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced positive results of its Phase 1 clinical trial investigating the safety and immunogenicity of VLA1601, its second-generation adjuvanted inactivated vaccine candidate against the Zika virus (ZIKV).

The randomized controlled Phase 1 trial, VLA1601-102, enrolled approximately 150 participants aged 18 to 49 years in the United States. Participants received two administrations, four weeks apart, of a low, medium or high dose of the highly purified inactivated aluminum-adjuvanted vaccine candidate VLA1601. In addition, the low dose of VLA1601 was evaluated with additional adjuvants, either the CpG 1018® adjuvant from Dynavax Technologies Corporation or the 3M-052-AF adjuvant from the Access to Advanced Health Institute (AAHI).

Data up to Day 57 (four weeks after the second dose (Part A Analysis)) showed that VLA1601 was generally safe and well tolerated in all five treatment arms, and no safety concerns were identified. Additionally, an independent Data Safety Monitoring Board did not reveal any safety issues.

Two doses of VLA1601 were immunogenic across all five treatment arms investigated (i.e., alum-adjuvanted Low, Medium and High antigen dose; Low with additional adjuvants). The strongest immune response was observed in the double-adjuvant treatment arms (Low+alum+3M-052-AF and Low+alum+CpG1018) with statistically significantly higher neutralizing antibody titers (Geometric Mean Titers - GMTs) at Day 43 and Day 57 than in the single-adjuvant (alum) treatment arm.

The immune response induced by the double-adjuvanted VLA1601 second generation vaccine candidate was successfully improved compared to the first-generation vaccine candidate with higher peak seroconversion rates (>93% vs 86%) and peak Geometric Mean Fold Increase of titers (>56 fold vs >7 fold). Phase 1 results from Valneva's first-generation Zika vaccine candidate were reported in 2018[1].

VLA1601 is developed on the original manufacturing platform of Valneva's licensed Japanese encephalitis vaccine IXIARO®, which was further optimized to develop the Company's inactivated, adjuvanted COVID-19 vaccine VLA2001.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "We are pleased by the notable safety and immunogenicity results demonstrated for our Zika vaccine candidate and especially our double-adjuvantation results. As global temperatures rise and rainfall patterns shifts, the expanding habitat of disease-carrying mosquitoes poses a growing public health challenge for infections such as Zika."

---

[1] *A randomized, placebo-controlled, blinded phase 1 study investigating a novel inactivated, Vero cell-culture derived Zika virus vaccine - PubMed (nih.gov)* and *Emergent Biosolutions and Valneva Report Positive Phase 1 Results for Their Vaccine Candidate Against the Zika Virus - Valneva*

Despite the medical need, regulatory pathways and market opportunities for potential Zika vaccines remain uncertain. Valneva will therefore only consider further potential development steps for VLA1601 if concrete major private and public funding opportunities materialize.

About the Zika Virus

The Zika virus (ZIKV) is a mosquito-borne flavivirus that was first discovered in 1947. The first human cases were detected in 1952. Since then, disease outbreaks have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and, in 2015, in the Americas. Zika virus is currently circulating in Mexico, Central and South America, in many countries and territories in the Caribbean region, and in a small number of geographically limited areas of the continental United States. To date, a total of 89 countries and territories have reported evidence of mosquito-born Zika virus transmission, though global surveillance remains limited. According to the World Health Organization (WHO), there is scientific consensus that ZIKV infection can cause congenital microcephaly and Guillain-Barré syndrome (GBS). Since 2013, 31 countries and territories have reported cases of congenital microcephaly and other central nervous system malformations associated with Zika virus infection.

About VLA1601

VLA1601 is a highly purified inactivated vaccine candidate against the Zika virus (ZIKV), developed on the original manufacturing platform of Valneva's licensed Japanese encephalitis vaccine IXIARO®, which was further optimized to develop the Company's inactivated, adjuvanted COVID-19 vaccine VLA2001, the first COVID-19 vaccine to receive a standard marketing authorization in Europe. Valneva reported positive Phase 1 results for VLA1601 in 2018[2]. The vaccine candidate was immunogenic and showed a favorable safety profile in all tested doses and schedules that was comparable to IXIARO® and other clinical stage ZIKV vaccines.

About Valneva SE

We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions. We have a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently market three proprietary travel vaccines. Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, the world's most clinically advanced Shigella vaccine candidate, as well as vaccine candidates against the Zika virus and other global public health threats. More information is available at www.valneva.com.

Valneva Investor and Media Contacts

Laetitia Bachelot-Fontaine
VP, Global Communications and European Investor Relations
M +33 (0)6 4516 7099
communications@valneva.com

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

[2] *A randomized, placebo-controlled, blinded phase 1 study investigating a novel inactivated, Vero cell-culture derived Zika virus vaccine - PubMed (nih.gov)* and *Emergent Biosolutions and Valneva Report Positive Phase 1 Results for Their Vaccine Candidate Against the Zika Virus - Valneva*

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, 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 in this press release will in fact be realized. Valneva is providing this information as of the date of this press release 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.