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

Valneva and LimmaTech Announce First Vaccination in Phase 2 Infant Study of Tetravalent Shigella Vaccine Candidate S4V2

Saint Herblain (France) and Schlieren (Zurich), April 9, 2025 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and LimmaTech Biologics AG, a clinical-stage biotech company developing vaccines for the prevention of life-threatening diseases, announced today that the first participant has been vaccinated in a Phase 2 infant safety and immunogenicity study of Shigella4V2 (S4V2), the world's most clinically advanced tetravalent bioconjugate vaccine candidate against shigellosis.

Shigellosis is the second leading cause of fatal diarrheal disease worldwide, strongly contributing to pediatric morbidity and mortality. It is estimated that up to 165 million infections are due to Shigella of which 62.3 million occur in children younger than five years[1]. Developing an effective vaccine to prevent this deadly disease is a public health imperative for many areas of the world.

In the Phase 2 study S4V02 (Identifier: NCT06523231), the safety and immunogencity of S4V2 will be tested in approximately 110 nine-month-old infants with the goal of identifying the best dose to be tested in a Phase 3 trial. Sponsored and conducted by LimmaTech, S4V02 is a randomized, controlled, and blinded study conducted at a single study site in Kenya. Participants will receive a two-dose vaccination with one of two different vaccine dose levels of S4V2 or a control vaccine. Safety will be evaluated throughout the trial for approximately six months following the last vaccination. Results of the study, which is supported by funding from the Gates Foundation, are expected in the second half of 2025.

Dr. Juan Carlos, Chief Medical Officer of Valneva, commented, "Seeing so many infants and children dying from shigellosis is not acceptable if it can be prevented with a vaccine. As such, the development of *Shigella* vaccines has been identified as a priority by the World Health Organization (WHO)[2] and, in line with our mission of developing vaccines against infectious diseases with unmet medical needs, we are focused on delivering a preventative solution against this deadly disease."

Dr. Patricia Martin, Chief Operating Officer of LimmaTech, stated, "We are proud to be in a leading position in the development of a *Shigella* vaccine, and the initiation of this trial marks a significant milestone in our collaboration with Valneva to combat shigellosis. We are encouraged by the potential of S4V2 to provide a solution for a serious global health threat and make a profound impact in protecting the health of so many children worldwide."

In November 2024, Valneva and LimmaTech announced vaccination of the first participant in a Phase 2b controlled human infection model (CHIM) study of S4V2 (Identifier: NCT06615375), in approximately 120 healthy *Shigella*-naïve participants aged 18 to 50 years[3]. This CHIM study

[1] *Shigellosis | CDC Yellow Book 2024*
[2] *Immunization, Vaccines and Biologicals (who.int)*
[3] *Valneva and LimmaTech Announce First Vaccination in Phase 2b Human Challenge Study of Tetravalent Shigella Vaccine Candidate S4V2 - Valneva*

forms part of the companies' staggered and risk-mitigating development strategy for S4V2, as it should provide the first results on efficacy before potentially advancing to further CHIM and Phase 3 studies.

The U.S. Food and Drug Administration (FDA) also granted Fast Track designation to S4V2[4], recognizing its potential to address a serious condition and fill an unmet medical need.

About Shigellosis

Shigellosis is a global health threat caused by the Gram-negative *Shigella* bacteria. It is estimated that up to 165 million infections[5] are due to *Shigella* of which 62.3 million occur in children younger than five years. Diarrheal infection is one of the major causes of morbidity and mortality in numerous countries as well as in travelers and deployed military personnel in endemic regions. There are an estimated 600,000 deaths attributed to *Shigella* each year and it is the second leading cause for diarrheal deaths[6]. The standard treatment for shigellosis is oral rehydration and antibiotic therapy, however, the bacteria have acquired resistance to many antibiotics with numerous reports of outbreaks of multidrug-resistant strains, making treatment extremely difficult. Currently, no licensed *Shigella* vaccine is available.

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, including the world's first chikungunya vaccine, as well as certain third-party 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 tetravalent 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.

About LimmaTech Biologics AG

LimmaTech Biologics is at the forefront of combating the global antimicrobial resistance epidemic based on its unparalleled track record in vaccine technology and clinical candidate development. The company is leveraging its proprietary self-adjuvanting and multi-antigen vaccine platform alongside additional disease-specific vaccine approaches to prevent increasingly untreatable microbial infections. With decades of expertise and an expanding, robust pipeline, the LimmaTech team is dedicated to generating protective solutions to deliver transformative value worldwide.

---

[4] *Valneva and LimmaTech Awarded FDA Fast Track Designation for Tetravalent Shigella Vaccine Candidate S4V - Valneva*

[5] *Shigellosis | CDC Yellow Book 2024*

[6] *Shigellosis | CDC Yellow Book 2024*

LimmaTech Biologics is backed by specialist healthcare investors, including Adjuvant Capital, AXA IM Alts, Novo Holdings REPAIR Impact Fund, and Tenmile.
For more information, please visit www.lmtbio.com.

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

For LimmaTech

LimmaTech Biologics AG
Franz-Werner Haas, CEO
E-mail: media@lmtbio.com

For media enquiries

Trophic Communications
Gretchen Schweitzer or Jacob Verghese
Phone: +49 172 861 8540
E-mail: limmatech@trophic.eu

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.