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Valneva and LimmaTech Enter into a Strategic Partnership to Accelerate the Development of the World's Most Clinically Advanced Tetravalent Shigella Vaccine Candidate

- **Valneva obtains exclusive worldwide license for LimmaTech's S4V *Shigella* vaccine candidate and adds an attractive Phase 2 clinical asset to Valneva's R&D pipeline**
- **LimmaTech to receive upfront payment, is eligible for future milestone and royalty payments, and will collaborate on S4V clinical development through Phase 2**
- **Valneva will host a live webcast on this announcement at 3 p.m. CEST/9 a.m. EDT today. Please refer to this link:** https://edge.media-server.com/mmc/p/ck932u2n

Saint-Herblain (France) and Schlieren (Zurich), August 1, 2024 – 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, today announced that the companies have entered into a strategic partnership and exclusive licensing agreement for the development, manufacturing and commercialization of Shigella4V (S4V), a tetravalent bioconjugate vaccine candidate against shigellosis.

Shigellosis, caused by *Shigella* bacteria, is the second leading cause of fatal diarrheal disease worldwide. It is estimated that up to 165 million cases of disease and an estimated 600,000 deaths are attributed to *Shigella* each year[1], particularly among children in Low- and Middle-Income Countries (LMICs). No approved *Shigella* vaccine is currently available and the development of *Shigella* vaccines has been identified as a priority by the World Health Organization (WHO)[2]. Shigellosis also affects international travelers from high-income countries and deployed military personnel in endemic regions. The global market for a vaccine against *Shigella* is estimated to exceed $500 million annually[3].

Under the terms of the agreement with Valneva, LimmaTech will receive an upfront payment of €10 million and be eligible to receive additional regulatory, development and sales-based milestone payments as well as low double-digit royalties on sales. LimmaTech will be responsible for conducting a Phase 2 Controlled Human Infection Model (CHIM) and a Phase 2 pediatric study in LMICs. Both clinical trials are expected to begin in the second half of 2024. Valneva will

[1] *Shigellosis | CDC Yellow Book 2024*
[2] *Immunization, Vaccines and Biologicals (who.int)*
[3] *Valneva's Initial internal assessment*

assume all further development, including CMC (chemistry, manufacturing and controls) and regulatory activities, and be responsible for its commercialization worldwide if approved.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "We are very pleased to partner with LimmaTech to advance a promising program in an area of high unmet medical need. The *Shigella* vaccine candidate enables a potential first-in-class vaccine solution for both LMICs and travelers and, as such, represents a potentially highly synergistic product for Valneva. The anticipated development path follows a staggered and risk-mitigated strategy, and hence allows an efficient capital allocation in line with our communicated plan of having a new R&D program in Phase 3 by 2027."

Dr. Franz-Werner Haas, Chief Executive Officer of LimmaTech, said**,** "Having developed the S4V *Shigella* vaccine candidate from its early discovery phase to the promising clinical data we achieved to date, we are excited to accelerate the program with our partnership with Valneva. Their proven expertise in late-stage development and commercialization of vaccines will expedite potential market approval and bring a *Shigella* vaccine to people in need. This agreement underscores our capabilities to leverage LimmaTech's proficiency in vaccine development with the best path to develop programs rapidly. We continue to expand our pipeline of vaccine candidates to combat microbial-based infectious diseases, providing protection against antimicrobial resistance, a dramatically increasing global health threat."

LimmaTech initiated the tetravalent *Shigella* vaccine candidate and continued to lead its development as part of its ongoing collaboration with GSK, and later in-licensed the vaccine candidate from GSK. In February 2024, LimmaTech reported positive interim Phase 1/2 data for the S4V vaccine candidate, including a favorable safety and tolerability profile as well as robust data on immunogenicity against the four most common pathogenic *Shigella* serotypes, *S. flexneri* 2a, 3a, 6, and *S. sonnei*[4]. The results of the completed Phase 1/2 study confirmed the interim data.

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.

[4] *20240221_LimmaTech_Shigella-Interim-Data-PR_Final.pdf (lmtbio.com)*
[5] *Shigellosis | CDC Yellow Book 2024*
[6] *Shigellosis | CDC Yellow Book 2024*

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 and only 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, 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. 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.

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to business partnerships, 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 financing environment, 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.