LimmaTech Biologics Reports Positive Interim Phase I/II Clinical Data on Tetravalent *Shigella* Bioconjugate Vaccine S4V

- Preliminary data from 472 nine-month-old infants confirm favorable safety and tolerability profile and demonstrate significant immunogenicity for the four most common pathogen serotypes
- Results support further development with LimmaTech expecting to initiate the next clinical trial in 2024
- Topline results from the completed Phase I/II will be reported in the first half of 2024

Schlieren (Zurich), 22. February 2024 - LimmaTech Biologics AG announced positive interim data from its Phase I/II clinical trial evaluating Shigella4V (S4V), a tetravalent bioconjugate vaccine candidate against shigellosis, an infectious disease caused by *Shigella* bacteria. Shigellosis is a serious infection and remains the second leading cause of fatal diarrheal disease, particularly in infants in low- and middle-income countries. In the nine-month-old target population, administration of S4V demonstrated 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*. Topline data from the now completed Phase I/II trial, conducted in Kenya, are expected in the first half of 2024.

LimmaTech's S4V vaccine candidate demonstrated initial safety in all age groups evaluated already in the first part of the clinical trial. The current data update from the second part of the clinical trial includes 472 infants (nine months ± one month) who received two intramuscular injections at one of four different dose levels with or without the addition of an adjuvant. S4V was well tolerated with the majority of local and systemic reactions reported being mild in intensity and similarly distributed between the different groups. No vaccine-related serious adverse events (SAEs) were reported. A statistically significant increase in serum IgG levels was obtained after either the first or the second injection, depending on the dose and formulation used.

"These positive interim results with S4V establish the very good immunogenicity that our bioconjugate vaccine candidate can generate in nine-month-old infants, a population that needs it the most," commented **Patricia Martin, PhD, Chief Operating Officer of LimmaTech.** "Shigellosis is a serious disease caused by a pathogen continuously evolving and becoming increasingly resistant to antibiotics. Our vaccine candidate has the potential to prevent an infection that threatens the lives of many children as well as protect travelers and military personnel traveling to *Shigella*-endemic countries. We look forward to continuing its clinical development in a study we plan to initiate in 2024."

The interim Phase I/II data were previously presented at the BactiVac 4th Annual Network Meeting 2023 held in Birmingham, UK.

About the Phase I/II study

Conducted in Kenya, the Phase I/II study is a randomized, double-blind, dose-finding, and age-descending clinical trial designed to assess the safety and immunogenicity of Shigella4V (S4V). The clinical trial is divided into two parts. The Part 1 age-descending study evaluated the vaccine candidate's safety in adults, children (two-five years), and infants. The Part 2 dose-finding study evaluates S4V's safety and immunogenicity in the nine-month-old target population to identify the preferred vaccine dose.

In 2015, LimmaTech signed a research collaboration agreement with GlaxoSmithKline (GSK) to develop novel, bioconjugate antigen-based vaccines, including a monovalent *Shigella* vaccine to be developed with the support of the Wellcome Trust. Following positive results from the proof-of-concept clinical trial with the monovalent *Shigella* vaccine, LimmaTech and GSK initiated the development of a multivalent *Shigella* vaccine funded in part by a Wellcome Trust grant. In July 2023, LimmaTech announced that it had in-licensed the S4V *Shigella* bioconjugate vaccine candidate from GSK to lead the further development of the program.

About Shigellosis:

Shigellosis is a global health threat caused by the Gram-negative *Shigella spp.* bacteria. It is estimated that about 188 million infections are due to *Shigella* of which 62.3 million cases occur in children younger than 5 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 600,000 deaths attributed to *Shigella* each year and it is the second leading cause for diarrheal deaths. 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 LimmaTech Biologics

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. For more information, please visit www.lmtbio.com.

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