# GSK Grants LimmaTech Biologics License to Develop and Commercialize *Shigella* Vaccine

- LimmaTech in-licenses *Shigella* bioconjugate vaccine from GSK to continue its clinical development; Phase I/II study completion and results are expected in 2023
- Currently, there are no vaccines to help prevent shigellosis, a disease which causes 600,000 deaths each year. With the pathogen developing resistance to the antibiotics used to treat it, there is an urgent need for a vaccine to prevent the disease.

**Schlieren (Zurich), 20 July 2023** - LimmaTech Biologics AG ("LimmaTech Bio"), a clinical-stage biotech company developing vaccines for the prevention of life-threatening diseases, signed an in-license agreement with GlaxoSmithKline Biologicals SA (LSE/NYSE: GSK) enabling LimmaTech Bio to further develop and commercialize a quadrivalent bioconjugate vaccine candidate for shigellosis that GSK added to its infectious disease pipeline when LimmaTech Bio's predecessor company, GlycoVaxyn, was acquired by GSK in 2015.

Shigellosis is a serious diarrheal infection and global health threat with a major impact in low- and middle-income countries where mortality and morbidity are high. The multivalent vaccine candidate being developed is composed of antigens from the four most epidemiologically relevant *Shigella* bacterial strains and is being tested in an ongoing Phase I/II dose-finding and age-descending (adults-children-infants) double-blind study to evaluate its safety and immunogenicity in the 9-month-old infants target population.

"LimmaTech Bio has remained committed to developing our *Shigella* vaccine candidate and this agreement with GSK has its roots in our successful ongoing partnerships with them. We have been a part of the *Shigella* vaccine program's journey together with GSK and the Wellcome Trust and the agreement recognizes and validates our in-house expertise in vaccine development as well as our capabilities to move the program forward rapidly," **said Patricia Martin, PhD, Managing Director and Vice President of Clinical and Regulatory Affairs at LimmaTech Bio**. "Based on the promising results of the monovalent version, we are looking forward to the data from the 4-valent form of the vaccine, which we expect in 2023. It is now more than ever critical to have a vaccine against a pathogen that is increasingly becoming resistant to antibiotics and represents a high unmet need, especially in young children."

LimmaTech Bio is an independently owned Swiss biotechnology company that spun out from GlycoVaxyn after its acquisition by GSK in 2015. LimmaTech Bio signed a research collaboration agreement with GSK to develop novel bioconjugate antigen-based vaccines including a monovalent *Shigella* vaccine in cooperation with the Wellcome Trust. Following

positive results from the proof-of-concept human challenge clinical trial with the monovalent *Shigella* vaccine, LimmaTech initiated the development of a multivalent *Shigella* vaccine in 2018 with a Wellcome Trust grant received by GSK for the new program. The results from the Phase I/II study with this multivalent vaccine are expected in 2023. A positive outcome for safety and immunogenicity will support the further development of the vaccine with pivotal efficacy trials in the target pediatric population as well as travelers and military personnel traveling to *Shigella* endemic countries.

**Thomas Breuer, Chief Global Health Officer at GSK,** added, "At GSK, we're committed to changing the trajectory of high-burden infectious diseases that disproportionately affect underserved people in lower-income countries. Partnering with the team at LimmaTech Bio to further the development of this *Shigella* vaccine candidate is a great example of how we can do that. LimmaTech will give this candidate vaccine the greatest chance of success, while GSK continues to use its expertise to progress another vaccine in clinical development using a GSK proprietary vaccine platform technology called GMMA. Having more than one vaccine could improve supply security and enable countries to implement the one that best suits their particular needs. Together, we can get ahead of *Shigella*."

Shigellosis is a global health threat caused by any one of four Gram-negative *Shigella spp.* bacteria, including *S. dysenteriae, S. sonnei, S. flexneri,* and *S. boydii*. 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, which makes treatment extremely difficult. Currently, no licensed *Shigella* vaccine is available.

**About LimmaTech Biologics AG**

LimmaTech Biologics AG is applying its deep know-how of engineering complex carbohydrate molecules to develop next-generation vaccines to prevent life-threatening diseases. Spun out from GlycoVaxyn after that company's acquisition by GSK, LimmaTech Bio is advancing its own proprietary clinical pipeline to halt the increasing threat of global infections due to emerging antimicrobial resistance and sexually transmitted infections such as gonorrhea, alongside partnered programs with GSK. LimmaTech is committed to translating novel scientific concepts into commercially available vaccines that benefit humanity.

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

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