

## **LimmaTech Awarded FDA Fast Track Designation for Vaccine Candidate Against *Staphylococcus aureus***

Schlieren (Zurich), December 19, 2024 – [LimmaTech Biologics AG](https://www.limmatech.com), a clinical-stage biotech company developing vaccines for the prevention of life-threatening diseases, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to LimmaTech’s multivalent toxoid vaccine candidate, LBT-SA7, designed to prevent skin and soft tissue infections (SSTIs) caused by the bacterial pathogen, *Staphylococcus aureus* (*S. aureus*).

The FDA grants Fast Track designation to products under development that have the potential to treat or prevent serious conditions and address an unmet medical need. The Fast Track designation is designed to expedite the review by enabling LimmaTech to engage more frequently with the FDA to discuss LBT-SA7’s clinical development plan. The designation aims to get important new products to patients and individuals earlier.

**Dr. Franz-Werner Haas, Chief Executive Officer of LimmaTech**, commented, “*Staphylococcus aureus* infections are a major cause of global mortality and morbidity, with traditional antibiotic treatments becoming increasingly ineffective due to rising antibiotic resistance. Despite this urgent medical need, no vaccine is currently available to prevent the consequences of an *S. aureus* infection. The FDA’s Fast Track designation for LBT-SA7 allows us to accelerate the development of a much-needed solution for SSTIs by effectively preventing recurrence.”

It is estimated that more than 1 million deaths are attributed to *S. aureus* each year. Notably, 90% of all community-acquired *S. aureus* infections are SSTIs, which LBT-SA7 aims to address. The vaccine candidate contains weakened forms of the pathogen’s toxins, referred to as toxoids, to prevent infections by neutralizing the toxins the pathogen would otherwise secrete to cause an infection.

“LBT-SA7 represents a fundamentally novel approach to Staphylococcal vaccine development, designed to neutralize toxins and prevent their harmful effects on affected people,” explained **Dr. Michael Kowarik, Chief Scientific Officer of LimmaTech**. “Our Phase 1 clinical trial aims to demonstrate the safety of our vaccine candidate in healthy volunteers and confirm the toxin-neutralizing activity induced by the vaccine.”

LBT-SA7 will be tested in a randomized, double-blinded, and controlled dose-escalation Phase 1 study at a clinical trial center in the U.S., including 130 participants aged 18-50 years. The trial aims to evaluate the safety and immunogenicity of the vaccine candidate, with initial results anticipated in the second half of 2025.

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*of the Global Antimicrobial Resistance Innovation Fund (GAMRIF). The content of this press release is solely the responsibility of the authors and does not necessarily represent the official views of CARB-X or any of its funders.*

### **About *Staphylococcus aureus***

*Staphylococcus aureus* (*S. aureus*), a Gram-positive bacterial pathogen, affects approximately 30% of the human population while causing a spectrum of infections, from SSTI to severe conditions like pneumonia and bloodstream infections. *S. aureus* is the leading cause of antimicrobial resistance (AMR)-attributed fatalities with community-acquired and hospital-acquired infections being the most prevalent. SSTIs caused by *S. aureus* range from mild to severe and entail microbial invasion into the skin layers and underlying soft tissues. Traditional antibiotic treatments, both oral therapy and intravenous administration reserved for severe cases, have become increasingly less effective due to the rise of antibiotic resistance. *S. aureus* has been designated as a "high priority" pathogen by the World Health Organization (WHO), underscoring the urgency for innovative vaccine approaches and effective treatment strategies.

### **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](http://www.lmtbio.com).

### **Contacts**

#### **LimmaTech Biologics AG**

Franz-Werner Haas, CEO

E-Mail: [media@lmtbio.com](mailto:media@lmtbio.com)

#### **For media enquiries**

Jacob Verghese or Anja Heuer

Trophic Communications

Phone: +49 151 7441 6179

Email: [limmatech@trophic.eu](mailto:limmatech@trophic.eu)