Eveliqure Announces Dosing of First Participants in a Phase 2b study of the ShigETEC Vaccine in Shigellosis

- Phase 2b study to assess immunogenicity and efficacy of the oral ShigETEC vaccine against Shigellosis
- Study entails vaccination of participants followed by a Controlled Human Infectious Model (CHIM) with Shigella
- Study is conducted under US IND at the Johns Hopkins University, the world's most experienced clinical site for Shigella and ETEC CHIM studies, under a U.S. government contract from NIAID

Vienna, Austria, July 23, 2025 - Eveliqure Biotechnologies GmbH, a biotech company developing vaccines for the prevention of diarrhoeal diseases announced today that the first participants have been vaccinated in a Phase 2b efficacy study of ShigETEC, the world's most clinically advanced combination vaccine against shigellosis and enterotoxigenic *E. coli* (ETEC) infections.

Currently, no licensed vaccines to prevent infections from Shigella or ETEC are available. These two pathogens are the leading causes of bacterial diarrhoeal diseases worldwide and cause an estimated 200 million diarrhoea cases in children under five years of age in low- and middle-income countries. In this most vulnerable population, there is an unacceptable high mortality rate and long-term consequences on growth and development (stunting) due to repeated infections. In addition, approximately 40% of travellers visiting disease-endemic countries, as well as deployed military and disaster response personnel are affected with severe interruption in daily activities. The emergence and spreading of multi-drug resistant Shigella strains worldwide, reported by CDC and WHO, is alarming and severely restricts antibiotic options for treatment.

ShigETEC, an oral live, attenuated vaccine candidate, targets both Shigella and ETEC infections. It is based on an engineered Shigella vaccine strain that lacks invasiveness into gut epithelial cells, a hallmark of shigellosis, and also lacks sugar antigens on the bacterial surface that drive narrow-spectrum immune responses. In addition, the vaccine strain carries ETEC antigens to induce protective antibodies that inactivate powerful diarrheagenic toxins. Based on the favourable tolerability and immunogenicity profile defined in the Phase 1a study (NCT05409196) conducted previously in adults in Europe, Eveliqure is moving forward with the development of ShigETEC. The vaccine is currently being tested in a Phase 1b study in Bangladesh (Identifier: NCT05987488), now with infants (6-11 months), after its safety has been proven in endemic adults, small children (2-5 years) and toddlers (12-23 months).

The ongoing Phase 2b controlled human infection model (CHIM) study (Identifier: NCT07049159) is a randomized, double-blind, placebo-controlled trial enrolling 60 healthy, Shigella-naïve adults aged 18 to 50. This study is a key element of Eveliqure's staggered, risk-mitigated development strategy, designed to deliver the first efficacy data against Shigellosis ahead of potential expansion to CHIM studies targeting ETEC and additional Shigella serotypes, and subsequent Phase 3 trials. Efficacy results are expected in the third quarter of 2026.

"With the launch of this Phase 2b trial, we're moving from possibility to proof - testing not just safety and immunogenicity, but the ShigETEC's real-world potential", said Dr. Gábor Somogyi, Chief Executive Officer of Eveliqure. "This Phase 2b study together with the ongoing Phase 1b study with infants, marks a critical step toward a global solution of Shigellosis - not with treatment, but with prevention where it's needed most".

"We are proud to be at the forefront of developing a combined broad-spectrum Shigella and ETEC vaccine and honored to collaborate with expert vaccine teams worldwide who share our mission to deliver a long-awaited solution to the global burden of diarrheal diseases.", commented Dr. Eszter Nagy, Co-Founder and President of Eveliqure.

The Phase 2b study is being conducted at the Johns Hopkins University (Baltimore, MD, USA) and supported by a U.S. government contract (#75N93020C00048) from the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health, awarded to Eveliqure. The Phase 1b tolerability, dose finding and immunogenicity study is being conducted in collaboration with icddd'r in Dhaka, supported by a the Horizon2020 grant awarded to the SHIGETECVAX consortium (grant number: 815568).

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ABOUT EVELIQURE

Eveliqure Biotechnologies (www.eveliqure.com) is a clinical-stage biotechnology company developing innovative vaccines to prevent infectious diseases with significant global impact. Using proprietary vaccine technologies, Eveliqure is advancing candidates against enteric pathogens such as Shigella and enterotoxigenic *Escherichia coli* (ETEC) - major causes of diarrheal illness in both low-resource settings and among travelers from high-income countries. In addition to addressing unmet needs in global health, Eveliqure is targeting the travel health market with safe and effective preventive solutions. Headquartered in Vienna, Austria, the company is supported by CEBINA (Central European Biotech Incubator and Accelerator, www.cebina.eu), a Vienna-based incubator that drives the translation of scientific innovation into healthcare solutions through an ecosystem designed to enable capital-efficient, accelerated development of biotech ventures.

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