

# Evelique initiates clinical safety and immunogenicity trials of its vaccine candidate against Shigellosis and ETEC in endemic populations in Bangladesh

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Evelique Biotechnologies GmbH, a clinical stage biotechnology company, announces the commencement of a Phase 1b clinical trial with ShigE<sub>TEC</sub>, its vaccine candidate against shigellosis and Enterotoxigenic *E. coli* (E<sub>TEC</sub>) diseases, in Bangladesh.

Shigella and E<sub>TEC</sub> are leading bacterial causes of diarrhoeal diseases worldwide, causing an estimated 200 million diarrhoea cases in children under five years of age. Infection with Shigella and E<sub>TEC</sub> can cause stunted growth among children, which has been linked to detrimental long-term health, developmental, and economic outcomes. No effective vaccines against these two pathogens exist and previous attempts to develop vaccines against Shigella and E<sub>TEC</sub> have failed.

Evelique is developing ShigE<sub>TEC</sub> both as a vaccine for children living in developing countries and for travellers to endemic regions. ShigE<sub>TEC</sub> is a live, attenuated oral vaccine candidate that was demonstrated to be well-tolerated and safe across all dose groups tested in a Phase 1a clinical trial conducted in Hungary. The placebo-controlled, dose-escalating, age-descending Phase 1b clinical study will focus on assessing the safety, tolerability and immunogenicity of ShigE<sub>TEC</sub> at the icddr,b (International Centre for Diarrheal Disease Research, Bangladesh) Clinical Trials Unit in Mirpur, Dhaka Metropolitan area, Bangladesh. The vaccine candidate will be first tested in healthy adult volunteers and subsequently in healthy children (2-5 years), toddlers (12-23 months) and infants (6-11 months). These activities are supported by the EU-funded SHIGETECVAX international consortium of several organizations - Evelique Biotechnologies, icddr,b, the European Vaccine Initiative, University of Gothenburg, and PATH.

Gábor Somogyi, MD, MBA, Chief Executive Officer of Evelique, commented "The initiation of the Phase 1b clinical trial is a pivotal moment for Evelique and represents a significant stride towards our goal of providing a safe and effective vaccine against Shigella and E<sub>TEC</sub>. Bangladesh, with its unique epidemiological landscape, offers an ideal setting for assessing our vaccine's performance in a population where the diseases are endemic and we are particularly glad to have this study run at the icddr,b's leading endemic clinical study site. We are optimistic about the potential impact of our vaccine on public health in this region and beyond."

Evelique is currently preparing for Phase 2 clinical trials in the U.S., under 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. This contract funds the Phase 2 testing of ShigE<sub>TEC</sub> in controlled human challenge models to assess the prophylactic efficacy against Shigella and E<sub>TEC</sub> infections.

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## ABOUT EVELIQUE

Evelique is a clinical-stage Austrian biotechnology company that has developed a proprietary vaccine technology platform aiming at improving the quality of life for both the poor and the privileged by providing innovative medical solutions to fight diarrhoeal diseases. Led by a team of experienced scientists and entrepreneurs, Evelique is committed in driving the development of novel technologies to make the world safe from diarrhoea.

Evelique is resident at CEBINA, the Central European Biotech Incubator and Accelerator ([www.cebina.eu](http://www.cebina.eu)). Evelique has received funding from the Austrian Research Promotion Agency (FFG) under grant numbers

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The Phase 1b trial in Bangladesh and the SHIGETECVAX Project have received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 815568 and from the Wellcome Trust under award number 212399/C/18/Z.

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