

Eveliqure announces the publication of positive Phase I clinical data for its vaccine candidate against Shigellosis and ETEC

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Eveliqure Biotechnologies GmbH, a clinical stage biotechnology company, today announces the publication of positive Phase I data with ShigETEC, its vaccine candidate against Shigellae and enterotoxigenic *E. coli* in the peer-reviewed journal *Vaccines* (<https://doi.org/10.3390/vaccines10020340>).

Currently no vaccines to prevent infections from Shigella and ETEC are available. These two pathogens are the leading causes of bacterial diarrhoeal diseases worldwide, affecting up to half of travellers to developing countries. In low- and middle-income countries, Shigella and ETEC have been estimated to cause 200 million diarrhoea cases in children under five years of age, and repeated infections with these pathogens can also have long-term consequences on children growth and development.

The published manuscript describes the evaluation of ShigETEC, a live, attenuated vaccine candidate given orally (drinkable), in a two-staged, randomized, double-blind and placebo-controlled Phase I clinical trial. ShigETEC 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 expected to induce protective antibodies that inactivate powerful diarrheagenic toxins. The maximum tolerated dose was determined with single doses of increasing amounts of vaccine, while multiple immunizations (two, three and four) with a fixed dose were administered with 3-day interval determined based on the duration of the shedding of the vaccine. The data demonstrate that oral immunization with ShigETEC was well tolerated and safe across the different dose groups tested. ShigETEC induced robust systemic immune responses (serum antibodies) against the Shigella vaccine strain as well as mucosal immunity. Anti-ETEC toxin antibodies were detected primarily in the 4-times immunized cohort and correlated with toxin neutralizing capacity.

“Our Phase 1 clinical data with ShigETEC demonstrate the validity of Eveliqure’s approach. Our non-invasive vaccine strain proved to be a successful response to the reactogenicity/safety problems experienced with previous generations of live Shigella vaccines, allowing immunization with high vaccine doses and thus inducing a strong immune response. Importantly, we have achieved the first ever demonstration of induction of effective immune responses (systemic or mucosal) to ETEC toxin in humans upon oral vaccination.” - commented Tamás Henics, MD, PhD, Co-Founder and Chief Scientific Officer of Eveliqure.

“These successful Phase 1 data represent a great achievement for Eveliqure and we are looking forward to further clinical testing. These data also strengthen our belief that ShigETEC has the potential to reduce the burden of diarrhoeal diseases for travellers, while also saving hundreds of thousands of children in endemic areas of the world”- commented Gábor Somogyi, MD, MBA, Chief Executive Officer of Eveliqure.

Eveliqure is developing ShigETEC both as a vaccine for travellers to endemic regions and for children living in developing countries. Eveliqure is planning safety and immunogenicity studies in children in endemic setting (supported by a H2020 grant for the SHIGETECVAX consortium) as well as Phase 2 controlled human challenge studies for efficacy for which Eveliqure has been awarded a US government contract from the National Institute of Allergy and Infectious Diseases (NIAID) (contract #75N93020C00048)

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ABOUT EVELIQUIRE

Eveliqure 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. Eveliqure has developed ShigETEC – a live, attenuated vaccine candidate designed to protect broadly against Shigella and ETEC infections in both travellers to and children living in low- and middle-income countries. Eveliqure is resident at CEBINA, the Central European Biotech Incubator and Accelerator (www.cebina.eu).

www.eveliqure.com

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