



International partnership to advance the clinical development of a new vaccine against Shigella and ETEC

Horizon2020 award to consortium will support the testing of an innovative live attenuated vaccine in phase I clinical trials in Europe and Bangladesh

Heidelberg, 10 September 2019

Although prophylactic vaccination is an effective way to reduce the huge disease burden associated with diarrhoea caused by enteric pathogens such as typhoid, cholera, and rotavirus, many attempts to develop vaccines for shigellosis and ETEC infections have failed, and a number of current approaches are too complex and costly to provide an adequate solution for low and middle income countries (LMICs).

Under coordination by the European Vaccine Initiative (EVI), the SHIGETECVAX consortium, made up of partners including EVI, EveliQure Biotechnologies, icddr,b, University of Gothenburg, and PATH, is dedicated to advancing a radically new approach developed by EveliQure Biotechnologies against Shigella and ETEC, one that is not based on the immunodominant, but highly variable Shigella LPS O-antigen that has been the target of almost all past and current vaccine development efforts.

According to Dr Frank Malinoski, MD, PhD, Chief Medical Officer at EveliQure Biotechnologies, “our innovative approach has enabled us to create the only combination vaccine which provides serotype independent protection for Shigella as well as ETEC. We look forward to working with this world-leading consortium at this important stage of development.”

The work programme of the new project entails manufacture of clinical trial material, first-in-human testing for safety and immunogenicity in non-endemic adults, a sero-epidemiology study to learn about natural immune response to the vaccine antigens that will help predict critical vaccine responses for this and future generations of Shigella and ETEC vaccines, feasibility studies of vaccine formulations specifically tailored for LMICs, and importantly testing the vaccine in endemic populations, including infants who are the major target population for Shigella and ETEC vaccines.

Dr. Hilde Depraetere, Acting Executive Director of EVI, points out that “the strategy chosen by EveliQure in the design of the vaccine indeed explores the challenge of developing vaccines against Shigella and ETEC from a new angle. In combination with the new formulation of the vaccine that we plan to develop in the project, overall this represents a promising approach for developing an affordable vaccine for these two diseases”. Dr. Depraetere adds that EVI plans to strengthen the organisation’s involvement in field of diarrheal diseases in the future.

It is expected that the phase I clinical trial will start in Europe during the first half of 2020 and foreseen to start in Bangladesh in 2021.

Quick facts about SHIGETECVAX:

Start Date: 01 September 2019

End Date: 31 August 2024

Coordinator: European Vaccine Initiative (EVI)

Project Funder: This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 815568.

Total Funding: 8.6M EUR

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SHIGETECVAX partners:

The European Vaccine Initiative (EVI) (<http://www.euvaccine.eu/>), established in 1998, is a leading non-profit organisation supporting the development of effective, accessible, and affordable vaccines for global health. Through promoting innovative solutions for disease control involving their global partner network of partners, EVI is striving for a world free of the intolerable burden of diseases of poverty within the coming decades. Since its inception in 1998 EVI has contributed to the development and clinical assessment of nearly 40 different vaccine preparations. EVI operates with support from the European Commission, the European & Developing Countries Clinical Trials Partnership (EDCTP), the Innovative Medicines Initiative (IMI), the Global Health Innovative Technology Fund (GHIT), the Coalition for Epidemic Preparedness Innovations (CEPI) and others. EVI is hosted by Heidelberg University in Germany.

EveliQure Biotechnologies (<http://www.eveliqure.com/>) **EveliQure Biotechnologies** (<http://www.eveliqure.com/>) is an Austrian based biotech company that is the game-changer amongst vaccine companies, championing novel technologies to make the world safe from diarrhoea. EveliQure is passionate about improving the quality of life for both the poor and the privileged by providing innovative medical solutions that fight diseases of all walks of life.

icddr,b (<https://www.icddr.org/>) has the world's most experienced clinical research team for evaluating diarrhoeal vaccines in LMICs and characterization of immune responses to ETEC and Shigella in endemic region.

University of Gothenburg (<https://www.gu.se/english>) and the team of Dr Ali Harandi (UGOT) who is a renowned expert in mucosal vaccines and vaccine-induced response evaluation with his experience in academic and translational immunology research to mucosal pathogens, as well as his involvement in multi-disciplinary international research and development programs strengthen our consortium.

PATH (<https://www.path.org/>) PATH is a global organization that works to accelerate health equity by bringing together public institutions, businesses, social enterprises, and investors to solve the world's most pressing health challenges. With expertise in science, health, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales solutions—including vaccines, drugs, devices, diagnostics, and innovative approaches to strengthening health systems worldwide. PATH will be involved in oral vaccine formulation studies, will perform the oral formulation development and will lead the development of a target product profile.