



EUROPEAN VACCINE INITIATIVE



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Developing vaccines for global health

EVI and Hilleman Laboratories announce partnership to assess a new vaccine against *Shigella*

Funding from European and Developing Countries Clinical Trials Partnership (EDCTP) will allow testing of a novel whole-cell inactivated oral vaccine in clinical trials in Europe and Africa

Heidelberg and New Delhi, 7 October 2019

The European Vaccine Initiative (EVI) and Hilleman Laboratories today announced that a multidisciplinary, international consortium coordinated by EVI has now received support from the European and Developing Countries Clinical Trials Partnership (EDCTP) to advance a safe, efficacious and affordable *Shigella* vaccine being developed by Hilleman Laboratories. The project will be funded by EDCTP through a grant of €8.6 million.

Elaborating about the project, Dr. Stefan Jungbluth, Head of Business Development at EVI, said, “Through this project we aim to further develop a novel oral vaccine against *Shigella* that we expect will cover the commonly isolated pathogenic strains of this bacteria. This vaccine, pioneered by our partner, Hilleman Laboratories from India, has been optimised for use in low resource settings. It has a cost-of-goods advantage and is easy to manufacture and deliver.”

Dr. Davinder Gill, CEO, Hilleman Laboratories said, “Hilleman Labs has developed a low-cost, easy-to-administer *Shigella* vaccine in collaboration with National Institute of Cholera and Enteric Disease (NICED) Kolkata and Indian Council of Medical Research (ICMR) Institute, New Delhi, India. Considering the huge disease burden carried by *Shigella*, and given that there is no licensed vaccine currently available to address the disease, we are pleased to partner with EVI to further advance our vaccine with funding support from EDCTP and technical support of our consortium members. ShigOraVax will be the first-ever Indian vaccine developed to benefit people living in low and middle-income settings. We look forward to testing safety and immunogenicity of our vaccine and to establish clinical proof-of-concept in endemic setting”.

Shigellosis is an acute enteric infection caused by consumption of food and water contaminated with bacteria from the genus *Shigella*. It is one of the leading causes of diarrhoea resulting in 165 million cases each year, and more than 212,000 deaths in all age groups[†]. It is reported as the second most common cause of diarrhoeal deaths in children under five years of age, after rotavirus. More than 50% of the *Shigella* burden lies in Africa. Despite its importance as a cause of major disease burden, there is still no vaccine available for use against *Shigella*.

Vaccination has proven to be a key effective measure of preventing morbidity and mortality from childhood diarrhoeal diseases, as has clearly been shown by vaccines against the rotavirus, the most common cause of acute gastroenteritis in children. The introduction of rotavirus vaccines has been demonstrated to be highly effective for reducing the morbidity and mortality caused by rotavirus infections in countries that have made such vaccines part of their universal vaccination programmes.

Other partners in the project are Leiden University Medical Center, The Netherlands, the Groupe de Recherche Action en Santé, Burkina Faso, the Centre for Infectious Disease Research, Zambia, and the University of Gothenburg, Sweden.

Together, through this project, the partners intend to develop the new *Shigella* vaccine candidate up to mid clinical stage. Specific objectives of the project include the preparation and conduct of a Phase Ia/Ib clinical trial in European and African adults, followed by an age de-escalating Phase II trial in Burkina Faso, and a multi-centre phase IIb clinical trial in Burkina Faso and Zambia. Moreover, specific epidemiologic data will be generated on the incidence of *Shigella* disease in the two African countries among children under five.

Quick facts about ShigOraVax:

Start Date: 01 October 2019

End Date: 30 September 2024

Coordinator: European Vaccine Initiative (EVI)

Project Funder: EDCTP2

Total Funding: 8,6M EUR



E D C T P

This project is part of the EDCTP2 Programme supported by the European Union

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ShigOraVax partners:

European Vaccine Initiative (EVI) (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.

Hilleman Laboratories (www.hillemanlabs.org) was established as an equal joint venture by MSD and Wellcome Trust in 2009, located in New Delhi, India. Hilleman Labs is a global vaccine R & D organization committed to developing high impact, affordable vaccines for people in developing countries. Its translational research focuses on creating safe, affordable vaccines and delivery solutions that are highly effective and can be easily incorporated into immunization programs. Hilleman Lab's focus is on transforming ideas into products and technologies through translational R&D and by building partnerships with vaccine manufacturers. To date, its emphasis has been largely on vaccines against infectious diseases and innovative delivery technologies for low and middle-income countries.

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Leiden University Medical Center (www.lumc.nl) is a university medical center for research, education and patient care with a high-quality profile and a strong scientific orientation. It has a unique research practice, ranging from pure fundamental biomedical research to applied clinical research. LUMC is a center for medical innovation, committed to the advancement of health care and innovative education in line with the latest international insights and standards - and aims to play a nationally and internationally recognized leading role in improving medicine and the quality of health care and people's health. The health of the global population is one of the biggest challenges of our time. Therefore, LUMC believes in curing but also in prevention. Within the LUMC, the Leiden Controlled Human Infection Center is a node of expertise which performs first-in-human clinical trials to test novel vaccines as efficiently as possible and develops novel technologies to allow for downstream clinical development in endemic areas. Its state-of-the-art facilities are exploited to develop vaccines for the global population with a specific focus on poverty-related diseases.

Groupe de Recherche Action en Santé (GRAS) (www.gras.bf) is private research institute based in Ouagadougou existing under the laws of Burkina Faso, operating since 2008 in the field of health research with a focus on clinical research. The scientific staff of GRAS is multi – disciplinary with well proven skills in clinical trials. The staff has a sound knowledge on ethical principles in research involving human subjects and on International Conference for Harmonization – Good Clinical Practice (ICH – GCP). Laboratory staff is certified for the shipment of dangerous goods such as bio - specimen samples in compliance with the International Air Transportation Association (IATA) rules. The Data management team has a strong experience with several data management software. Thanks to its worldwide partnership GRAS has built a performant platform for Phase I to Phase IV trials. During this last decade, scientists from GRAS have carried out more than 25 clinical trials for various infectious diseases (Malaria vaccines, pneumococcal vaccines, Ebola vaccines, typhoid vaccine, etc.).

Centre for Infectious Disease Research in Zambia (CIDRZ) (www.cidrz.org) is an independent non-profit non-governmental organisation that is committed to answering key research questions

relevant to Zambia and the region. Established in 2001, CIDRZ provides a platform for coordinated development and deployment of state-of-the-art technologies and analyses, which can be utilized effectively for discovery, early development, and testing of clinical products. CIDRZ aims to improve access to quality healthcare in Zambia through innovative capacity development, exceptional implementation science and research and impactful and sustainable public health programmes. Over the years, the institution positioned itself as the best health research institution in Zambia through conducting field and facility-based implementation science, and clinical trials which has enables the organisation generate impactful evidence and frequently informs policy to improving the quality of health care delivery in Zambia and beyond.

CIDRZ collaborates with multiple global institutions and universities. Presently, CIDRZ is conducting 47 distinct studies and projects and is supported by a wide range of funders including, but not limited to the European & Developing Countries Clinical Trials Partnership (EDCTP), CDC-PEPFAR, UK-DFID, US NIH, Grand Challenge Research Fund (GCRF), Wellcome Trust, Bill & Melinda Gates Foundation and other philanthropies.

University of Gothenburg (www.gu.se) is one of the largest universities in Scandinavia. One of its areas of international strength is vaccines and related immunology, with world-leading expertise in mucosal vaccines and mucosal immunology. Its achievements include e.g. (i) the development of the first WHO-prequalified oral vaccine against cholera, and an oral vaccine against ETEC diarrhoea in phase 2b clinical testing; (ii) the development of many of the most used immunoassays in vaccine research (e.g. first use of ELISA in vaccinology, development of the ELISPOT method for assaying antibody- and cytokine-secreting cells, and the intestinal lavage method for measuring intestinal antibodies); and (iii) phase 1 to phase 4 clinical testing of vaccines in both high- and low-income settings. The UGOT team consists of senior experts with proven world-leading experience and expertise in oral vaccine and immunology R&D and support staff. UGOT has a wide global partner network including organisations engaged in vaccine R&D from both public and private sector and has long experience of participation and leadership in numerous EU- and otherwise funded vaccine projects.

References:

† *Lancet* **18**: 1229 (2018)