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LimmaTech Biologics announces the start of a Phase I/II Shigella trial in Kenya

Schlieren (Zurich), 9 September 2019 - LimmaTech Biologics AG today announced the start of a Phase I/II clinical trial in Kenya of a 4-valent candidate vaccine to help prevent diarrheal disease caused by the Shigella bacteria in children and infants in low and middle-income regions. This study is conducted in collaboration with GSK.

The Global Burden of Disease Consortium ranked Shigella as the second leading cause of diarrheal deaths in the world in 2015 and the third leading cause of diarrheal deaths in children younger than 5 years[1]. In addition to mortality, the disease can also cause a significant amount of post infective complications, developmental repercussions, cognitive impairment and negatively impact children's development. There is currently no licensed vaccine to help protect against diarrheal disease caused by the Shigella bacteria. The emergence of antibiotic resistance is a major threat for the treatment of this disease, as many shigellosis outbreaks have been reported by resistant strains of Shigella[2].

As presented at the Vaccines for Enteric Diseases (VED) 2017 conference, two preceding clinical studies supported by the Wellcome Trust have delivered promising results[3] (Riddle et al. 2016; A. Dreyer et al. 2017; K.R. Talaat et al. 2017). With this new Phase I/II study, LimmaTech, GSK, and the Wellcome Trust intend to progress this candidate vaccine against the four most relevant disease-causing strains of Shigella.

The aim of the study is to assess the safety and immunogenicity of the candidate vaccine in a dose-finding age-descending (adults-children-infants) double-blind and randomized control Phase I/II clinical trial with a total of approximately 600 participants at two Kenya Medical Research Institute (KEMRI) sites in Kenya. The data collected in this study will contribute to progress scientific understanding of the disease and might represent an important step in the development of a potential vaccine to help protect the most vulnerable population in lower income countries.

"After the encouraging trial results of the monovalent vaccine, we are very pleased that GSK and Wellcome are providing the support necessary to develop this tetravalent vaccine. Recently, the Shigella pathogen is receiving more attention and we are proud to have been a pioneer in bringing forward this important benefit to children and infants in affected countries," said Dr. Veronica Gambillara Fonck, CEO of LimmaTech.

Dr Thomas Breuer, Chief Medical Officer of GSK Vaccines, commented: "We are excited to see the quadrivalent Shigella candidate vaccine being progressed through the collaboration between LimmaTech, GSK and the Wellcome Trust. We believe we can best contribute to improving health

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[1] GBD Diarrhoeal Diseases Collaborators, "Estimates of global, regional, and national morbidity, mortality, and aetiologies of diarrhoeal diseases: a systematic analysis for the Global Burden of Disease Study 2015". *Lancet Infect Dis*. 2017; 17: 909-948

[2] M.Puzari et al, « Emergence of antibiotic resistant Shigella species: A matter of concern », in Journal of Infection and Public Health, vol 11, 4, July-August 2018; p.451-454

[3] Riddle, Mark S et al.: Safety and Immunogenicity of a Candidate Bioconjugate Vaccine against Shigella flexneri 2a Administered to Healthy Adults: a Single-Blind, Randomized Phase I Study. In *Clin Vaccine Immunol* 23 (12), (2016) pp. 908–917

globally by focusing on our science, and by forming strong partnerships to deliver innovations sustainably and fight one of the most serious threats for children's life in developing countries. In this instance, the unique expertise of LimmaTech in bioconjugation has enabled us to progress the Shigella candidate vaccine and we look forward to seeing the results of this trial".

Dr Jens Kieckbusch, from Wellcome, said: "A safe and effective Shigella vaccine, that targets four different strains of the disease, could significantly reduce the number of children in many low and middle income countries who are affected by this potentially fatal disease. Wellcome has supported LimmaTech's approach to Shigella vaccine development since 2013, and we are excited to see this version progress into an early clinical trial. This award forms part of our Affordable Innovations for Global Health Flagship, which aims to reduce the burden of enteric disease by accelerating the development and implementation of affordable technologies and interventions."

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About LimmaTech Biologics AG

LimmaTech Biologics is a privately owned, clinical stage biopharmaceutical company developing pharmaceuticals for both the treatment and prevention of life-threatening diseases. The company has an exclusive research and development agreement with GSK to develop the bioconjugation technology used to produce the Shigella candidate vaccine. For more information, please go to www.lmtbio.com.

About GSK

GSK – a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. GSK is the world's leading vaccine company, with a portfolio that helps protect people throughout life and an innovative pipeline of 16 vaccines in development. Our vaccines help prevent illnesses such as hepatitis A and B, diphtheria, tetanus, whooping cough, measles, mumps, rubella, polio, pneumococcal disease, influenza, shingles and meningitis. At GSK, more than 17,000 people worldwide deliver around two million vaccine doses per day to people in 158 countries. For further information, please visit www.gsk.com.

About Wellcome Trust

Wellcome exists to improve health by helping great ideas to thrive. We support researchers, we take on big health challenges, we campaign for better science, and we help everyone get involved with science and health research. We are a politically and financially independent foundation.

Publication bibliography

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K.R. Talaat; C. Alaimo; A.L. Bourgeois; R.W. Kaminski; A. Dreyer; C.K. Porter et al. (2017): Flexyn2a, A Candidate Bioconjugate Vaccine Against Shigella flexneri 2a Induces Protective Immune Response in a Controlled Human Infection Model. Vaccines for enteric diseases. VED. Albufeira, Portugal, 2017.