

CHIKUNGUNYA VACCINE DEVELOPMENT TOWARDS PHASE III TRIALS BOOSTED BY INNOVATE UK

Vienna, 5th September 2017 – The further development of a promising Chikungunya vaccine candidate by Themis Bioscience is now supported with 3 Mio. GBP by the United Kingdom's innovation agency, Innovate UK. Themis, the Vienna-based specialist for vaccine development, will use these funds to identify and validate a correlate of protection for its prophylactic Chikungunya vaccination candidate. Currently the candidate is tested in three parallel phase II clinical trials, including one that is performed in an endemic area for Chikungunya. Already last year Innovate UK supported the development of Themis' Zika vaccine candidate currently investigated in a phase I clinical trial.

Today, Themis Bioscience GmbH (Vienna, Austria), a company specialized in vaccine development, announced a 3 Mio. GBP funding received by the innovation agency of the United Kingdom, Innovate UK. The funds are earmarked for the further development of the company's prophylactic Chikungunya vaccine candidate, that currently is tested in three phase II clinical trials. Together with the National Institute for Biological Standards and Control (NIBSC, UK) the company will now gear the vaccine's development towards a phase III clinical trial. The vaccine candidate is based on Themis' proprietary Themaxyn® platform that uses a well-established measles vaccine vector.

Dr. Erich Tauber, CEO and founder of Themis comments: "Analyzing efficacy of a Chikungunya vaccine in a large scale phase III clinical trial as well as a subsequent licence application in fact requires a valid correlate of protection. Thanks to the support by Innovate UK we now have additional means to quickly identify and validate such correlates together with NIBSC."

In this joint project the NIBSC will develop a non-humane primate (NHP) challenge model that will be used for testing human sera. Following this, a small scale phase I clinical trial with Themis' prophylactic vaccine candidate will be conducted in the UK. The aim of this is to identify and validate a correlate of protection and to identify a protective antibody threshold against the Chikungunya virus.

One of the major advantages of the Chikungunya vaccine candidate of Themis is a validated as well as cost-efficient production process. The measles vector technology developed by Themis forms the basis of all current vaccine candidates advanced by the company. It allows a rapid upscaling of the very cost effective vaccine production process once the vaccine candidate has been determined. This ability is critical for a vaccine that is supposed to combat diseases such as Chikungunya from spreading in highly populated areas. Additionally, the backbone measles vaccine has already proven its high efficacy and safety in well over a billion individuals over the last 30–40 years, and the technology offers an excellent safety profile. Under the terms of a broad license agreement with the Institut Pasteur, Themis owns the rights to use the measles vector for a wide range of indications including Chikungunya and Zika.

Currently Themis' live attenuated prophylactic Chikungunya vaccine candidate is tested in two parallel phase II studies in both, the USA and Austria/Germany. An additional trial in Puerto Rico in collaboration with the Walter Reed Army Institute of Research (WRAIR), an institution of the US Department of Defense just commenced. This trial is intended to evaluate the influence of previous chikungunya infections on the safety and immunogenicity of the vaccine candidate. Erich Tauber on these trials: "All three trials combined well over 700 volunteers will receive our vaccine candidate. This will be a very substantial data set."

In the wake of the development of the Chikungunya vaccine and supported with another 1 Mio. GBP grant by Innovate UK last year the company also succeeded in advancing the development of a live attenuated recombinant Zika vaccine. Currently, this is tested in a phase I clinical trial at the Medical University of Vienna, Austria.

About Themis (September 2017):

Themis Bioscience GmbH develops prophylactic vaccines from the preclinical to the early clinical phase, focusing on emerging tropical infectious diseases, with initial vaccine candidates currently being developed against Chikungunya and Zika. The company's highly innovative and fully patent-protected measles virus vaccine vector technology platform forms the basis for all current vaccine candidates of the Vienna-based company.

www.themisbio.com

About the vaccine technology:

The core technology relies on the use of the standard measles vaccine as a vaccination vector. Genes coding for selected antigens from the Chikungunya virus have been inserted into the genome of this well-established vaccine. The measles-Chikungunya vaccine triggers the expression of the selected antigens which then are presented in macrophages and dendritic cells – the most potent and effective antigen-presenting cells, thereby triggering a specific immune response to Chikungunya virus. This results in a powerful, antigen-focused immune response, which is most likely to confer long-term immunity as does the measles vaccine.

About Innovate UK:

Innovate UK is the UK's innovation agency. It works with people, companies and partner organisations to find and drive the science and technology innovations that will grow the UK economy. For further information visit www.innovateuk.gov.uk

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