

PRESS RELEASE

Chikungunya-Fever:

Themis Bioscience Starts Phase II Clinical Study in Endemic Area

Vienna, Austria, 27 July -2017 – A promising prophylactic vaccine candidate against chikungunya fever will be tested from August on in a phase II clinical study in Puerto Rico, a chikungunya fever endemic area. Developed by the Austrian biotech company Themis Bioscience GmbH the live attenuated vaccine is considered as one of the most advanced candidates globally. It is based on a standard measles vaccination vector that offers an excellent immunogenicity and safety profile. The vaccine candidate already showed high seroconversion rates in the preceding phase I clinical trial: Up to 100 percent of all vaccinated subjects produced neutralizing antibodies against the chikungunya virus. Currently the vaccine candidate is tested in two parallel phase II studies in both, the USA and Austria/Germany. The additional trial in Puerto Rico is intended to evaluate the influence of previous chikungunya infections on the safety and immunogenicity of the vaccine candidate.

The biotech company Themis Bioscience GmbH (Vienna, Austria) today announced the start of a further Phase II clinical trial of a prophylactic vaccine for Chikungunya fever. Based on excellent data from a previous Phase I study this promising vaccine candidate already is tested in two ongoing Phase II clinical trials in the USA and Austria/Germany. The now commencing trial will focus on the influence of previous Chikungunya infections on the safety and immunogenicity and hence will be performed in Puerto Rico, a chikungunya fever endemic area.

Commenting on the trial, Dr. Erich Tauber, CEO and co-founder of Themis says: "Chikungunya virus remains a growing risk in many tropical areas. A prophylactic vaccine against Chikungunya is highly desirable and we are happy to offer this live attenuated vaccine candidate that many consider as the most advanced Chikungunya vaccine candidates worldwide. It is based on a standard measles virus vaccine as a vector that offers an excellent safety profile and clear advantages in terms of a validated, low-cost production process."

The new trial will be carried out in collaboration with the Walter Reed Army Institute of Research (WRAIR), an institution of the US Department of Defense. 100 volunteers will be vaccinated and over the period of a year will be tested for their immune responses and safety

parameters. One half of the volunteers will have experienced an previous infection with the Chikungunya virus whilst the other half will show no sign of previous infections. All volunteers will receive two jabs with one at study begin and a further one four weeks later.

Erich Tauber adds: "This current study will complement our two ongoing Phase II studies with additional data that are of specific importance for the safety of the vaccine in areas where Chikungunya fever is or has been endemic. Taking together in all three trials well over 700 volunteers will receive our vaccine candidate. This will be a very substantial set of data."

The prophylactic Chikungunya vaccine under development at Themis is based on a standard measles virus vaccine as a vector. This constitutes the basis of the company's pipeline that also includes a prophylactic Zika vaccine currently tested in a Phase I clinical trial in Austria. For the development of the live attenuated Chikungunya vaccine genes coding for selected antigens from the Chikungunya virus have been inserted into the genome of the well-established measles vaccine. Those new antigens are thus produced within the cells, thereby triggering a specific immune response against the Chikungunya virus. As measles vaccines have been successfully used in hundreds of millions of people globally it offers an excellent safety profile and clear advantages in terms of a validated, low-cost production process.

Chikungunya fever is a viral infection transmitted by specific mosquitoes. It originates in Asia and parts of Africa but the increase in global traveling and rising temperatures cause these mosquitoes and the viruses they carry to spread into more temperate zones. Within the last four years well over 1.7 million cases have been reported from 45 countries in the Americas and the Caribbean alone. The majority of infected persons develop severe polyarthralgias which can become chronic. Development of an effective vaccine is urgently needed and will significantly impact health costs for treatment of chronic diseases and disabilities.

About Themis (June 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, licensed from the internationally respected Institut Pasteur in Paris, forms the basis for all current vaccine candidates of the Vienna-based company. www.themisbio.com

About the vaccine technology:

The core technology of the measles vector platform has been developed at the Institut Pasteur in Paris and is licensed to Themis. It 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.

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