PRESS RELEASE

NIH and Themis Bioscience Announce the Initiation of a Clinical Trial of a Chikungunya Vaccine

Vienna, 06 June 2017 – A prophylactic vaccine candidate against Chikungunya fever developed with proprietary technology of Themis Bioscience GmbH will be tested in a clinical trial sponsored by the U.S. National Institutes of Health (NIH). The vaccine, developed by Themis, is based on a standard measles vaccine as a vaccination vector and hence offers an excellent safety profile. It already showed high seroconversion rates in the preceding Phase I clinical trial: 100 percent of all vaccinated candidates produced antibodies against the virus. This trial has started in May 2017 in the U.S. and is intended to provide data to support approval by the Food and Drug Administration (FDA). In Europe the vaccine is already tested in a clinical trial phase II since August 2016. The urgent need for a prophylactic vaccine is emphasized by recent Chikungunya outbreaks raging through the Caribbean and the Americas.

The biotech company Themis Bioscience GmbH (Vienna, Austria) today announced the start of a NIH-sponsored clinical trial of a prophylactic vaccine candidate against Chikungunya fever. The NIH's decision to sponsor the development of this urgently needed vaccine candidate was largely based on promising results of a previous Phase I clinical trial (published in The Lancet Infectious Diseases, DOI: http://dx.doi.org/10.1016/S1473-3099(15)70043-5). Data from this trial proved the safety and tolerability of the vaccine candidate and showed an high seroconversion rate for all patients after a second vaccination regardless of dosage. In order to support U.S. approval of the vaccine by the FDA, the forthcoming double-blinded randomized trial will be conducted exclusively in the U.S. and will focus on the induction of neutralizing antibodies as well as the T-cell response. For European approval by the European Medicines Agency, a Phase II clinical trial commenced in August 2016 and results are expected in the second half of 2017.

Commenting on the joint trial, Dr. Erich Tauber, CEO and founder of Themis says: "We are proud of the support of the NIH, which will sponsor the trial. In turn, Themis will provide all necessary doses of the vaccine in order to enroll up to 180 persons for this clinical trial and the clinical data will be used for regulatory purposes." The trial centers, which are funded by Vaccine and Treatment Evaluation Units (VTEU) contracts from the National Institute of Allergy

and Infectious Diseases (NIAID), a part of the NIH, will be at the University of Iowa in Iowa City, the Baylor College of Medicine in Houston as well as at the Emory University in Atlanta. There 180 persons will either receive the vaccine candidate (150 persons) or a placebo (30 persons) and three different treatment protocols using two different dosages will be applied. "The generous sponsoring of the trial by the NIH allows Themis also to gear further investments towards other vaccine candidates currently under development in our preclinical development pipeline", adds Dr. Tauber. The company recently announced the successful closing of a Series B financing round of EUR 10 Mio.

Themis' prophylactic Chikungunya vaccine is based on a measles vector platform, where selected antigens from the Chikungunya virus have been inserted into the well-established measles vaccine delivering those new antigens into the cells, thereby triggering a specific immune response against the Chikungunya virus. As the measles vaccine has already proven its high efficacy and safety on well over a billion individuals over the last 30–40 years, it offers an excellent safety profile and a validated, cost-efficient production process.

Chikungunya fever is a viral infection transmitted by mosquitoes. It originates in Asia and parts of Africa but the increase in global traveling and rising temperatures may cause it to spread into more temperate zones. Within the last three years well over 1,5 million case have been reported in the Americas and the Caribbean alone, highlighting the urgent need for an affordable prophylactic vaccine.

About Themis (March 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 (March 2017):
The scientific basis for Themis' measles vector Themaxyn® 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 delivers the chikungunya antigens directly to 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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