

Leading chikungunya vaccine in clinical trial phase 2

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With the first patient vaccinated, a phase 2 clinical trial of a promising prophylactic vaccine candidate against Chikungunya fever has now commenced. The product is the most advanced Chikungunya vaccine candidate globally and is developed by the Austrian biotech company Themis Bioscience GmbH. It is based on the company's proprietary Themaxyn platform, a standard measles vaccination vector developed in collaboration with the Institut Pasteur, that offers an excellent immunogenicity and safety profile. The vaccine candidate already showed high seroconversion rates in the preceding phase 1 clinical trial: Up to 100 percent of all vaccinated subjects produced neutralizing antibodies against the Chikungunya virus. In total 320 volunteers will be enrolled for this phase 2 dose confirmation study that is carried out in centers in Germany and Austria.

The biotech company Themis Bioscience GmbH (Vienna, Austria) today announced the vaccination of the first patient in a phase 2 clinical trial of a prophylactic <u>vaccine candidate</u> against Chikungunya fever. The study with 320 volunteers is a dose confirmation study and follows in the wake of a highly successful phase 1 clinical study that was recently published in *The Lancet Infectious Diseases*. The ongoing phase 2 trial will further confirm the immunogenicity of the vaccine and analyse indicators of efficacy such as functional antibodies and T-cell immune responses.

Commenting on the trial, Dr. Erich Tauber, CEO and co-founder of Themis says: "With outbreaks in many regions of the world, the Chikungunya virus remains a growing risk in endemic areas. A



prophylactic vaccine against Chikungunya is highly desirable and we are happy to be able to offer this important vaccine candidate that is now undergoing a phase 2 clinical trial." The trial will be carried out in centers in Berlin and Rostock (Germany) as well as in Vienna and Graz (Austria). 320 volunteers will receive either mid or high doses with study groups receiving a single injection and others two, spaced one month apart.

Erich Tauber adds: "This current study is aimed at the registration of our vaccine candidate on a world-wide basis. This study will be complimented by additional <u>phase</u> 2 studies currently under preparation in the US and the Carribean."

The prophylactic Chikungunya vaccine under development at Themis is based on the company's proprietary Themaxyn platform. It uses a standard measles virus vaccine as a vector that has been developed at the Institut Pasteur in Paris and constitutes the basis of the company's pipeline. Genes coding for selected antigens from the Chikungunya virus have been inserted into the genome of the well-established measles vaccine delivering those new antigens into 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, the Themaxyn platform 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 mosquitoes. It originates in Asia and parts of Africa but the increase in global traveling and rising temperatures cause it to spread into more temperate zones. Within the last three years well over 1.5 million cases have been reported in the Americas and the Caribbean alone, highlighting the urgent need for an affordable and effective prophylactic vaccine.

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 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.

More information: Katrin Ramsauer et al. Immunogenicity, safety, and tolerability of a recombinant measles-virus-based chikungunya vaccine: a randomised, double-blind, placebo-controlled, active-comparator, first-in-man trial, *The Lancet Infectious Diseases* (2015). DOI: 10.1016/S1473-3099(15)70043-5

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