

Sanofi dengue vaccine demonstrates proof of efficacy

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Singapore: The tetravalent dengue vaccine candidate of Sanofi Pasteur, the vaccines division of Sanofi, demonstrated proof of efficacy against dengue, a threat to almost three billion people, in the world's first-ever dengue efficacy trial conducted in Thailand, with excellent safety.

The vaccine generated antibody response for all four dengue virus serotypes. Evidence of protection was demonstrated against three of the four virus serotypes circulating in Thailand. Analyses are ongoing to understand the lack of protection for the fourth serotype in the particular epidemiological context of Thailand.

"Results of this first efficacy trial with Sanofi Pasteur's dengue vaccine candidate represent a key milestone in the quest to develop a safe and efficacious human vaccine against dengue," said Dr Michel De Wilde, executive vice president, Research & Development, Sanofi Pasteur. "This is also an important development for global public health, since there is currently no specific treatment or prevention for dengue. We are fully committed to making dengue a vaccine preventable disease by bringing a safe and effective vaccine to people living in endemic regions of the world."

Importantly, the results confirm the excellent safety profile of the vaccine candidate. The full data resulting from this first efficacy trial are currently under review by scientific and clinical experts, as well as public health officials. Detailed results of this study will be published in a peer-reviewed journal and presented to the scientific community later this year.

Large-scale phase III dengue vaccine clinical studies with 31,000 participants are underway in 10 countries of Asia and Latin America. These studies will generate important additional data in a broader population and in a variety of epidemiological settings to demonstrate vaccine efficacy against the four circulating dengue virus serotypes.

The study was conducted in 4,002 children aged 4 to 11 years, in partnership with the Mahidol University under the patronage of the Thai Ministry of Public Health in Muang district of the Ratchaburi Province. Sanofi Pasteur dengue vaccine candidate is a live attenuated vaccine. The vaccination schedule is three doses given six months apart

The US Food and Drug Administration (FDA) has granted fast-track designation to the company's investigational dengue vaccine. The FDA fast-track designation recognizes that a dengue vaccine would address an important unmet medical need for a serious disease.

The Sanofi Pasteur investigational dengue vaccine is intended for the prevention of dengue disease in children and adults living in endemic areas of Asia and Latin America as well as for children and adults who are travelling to endemic countries, including expatriates and military personnel.