PHASE III EFFICACY AND SAFETY STUDY OF SANOFI PASTEUR'S DENGUE VACCINE CANDIDATE IN ASIAN CHILDREN

THE FIRST OF TWO LANDMARK PHASE III STUDIES OF SANOFI PASTEUR'S DENGUE VACCINE CANDIDATE

ASIA PHASE III STUDY OVERVIEW

- The phase III clinical study conducted in Asia is a randomized, observer-blind, placebo-controlled, multicenter trial to assess the efficacy and safety of Sanofi Pasteur's dengue vaccine candidate in preventing dengue disease. The study is being carried out in five countries in Asia and includes 10,275 children aged from 2 to 14 years.[1]

STUDY OBJECTIVE

- The **primary objective** of the study was to assess the efficacy of the dengue vaccine candidate after three vaccinations in preventing symptomatic virologically-confirmed dengue cases, regardless of the severity.[1]

- The primary endpoint was the number of dengue cases (defined as acute febrile illness and virologically confirmed as dengue) that occurred more than 28 days after dose 3 during the 12 month active phase.[1] The safety objective was to evaluate the occurrence of serious adverse events (SAEs) including SAEs of special interest, in all subjects throughout the trial period.

STUDY METHODOLOGY

- 10,275 children aged between 2 and 14 years participated in the study
    - All volunteers were healthy (based on medical history and physical examination) and able to attend all scheduled study visits. An assent/informed consent form was signed and dated by the volunteer (age dependent), and an informed consent form had to be signed and dated by the parent(s) or another legally acceptable representative.[1]
    - Individuals with congenital or acquired immunodeficiency and those receiving immunotherapy or other vaccines were not eligible to take part in the study.[1]

- Children were randomized to either receive three injections of the dengue vaccine candidate or a placebo (2 to 1 ratio) at 0, 6, and 12 months.[1]

- A program of regular contact with volunteers and school based surveillance was implemented to ensure that as many as possible potential cases of symptomatic dengue were identified during the active phase. In addition, every child with an acute febrile illness (defined as temperature ≥38^{o}C on at least 2 consecutive days) was assessed to virologically-confirm whether they had dengue fever.[2]

STUDY LOCATION

- This phase III study was conducted in 12 sites across endemic areas of Indonesia (3 sites), Malaysia (2 sites), the Philippines (2 sites), Thailand (3 sites) and Vietnam (2 sites).[1]
    - Indonesia (Denpasar in Bali, Bandung in West Java, Jakarta)
    - Malaysia (Kuala Lumpur, Penang)
    - Philippines (Cebu, San Pablo)
    - Thailand (Muang District in Kamphaeng Phet Province, Ban Pong and Photharam Districts in Ratchaburi Province)
    - Vietnam (Long Xuyen in An Giang Province, My tho in Tien Giang Province)

LONG TERM FOLLOW UP

- Long-term follow-up with all volunteers will continue for five years after the completion of the third vaccination.[1]

References

[1] ClinicalTrials.gov. Study of a novel tetravalent dengue vaccine in healthy children aged 2 to 14 years in Asia. Available at: http://clinicaltrials.gov/ct2/show/NCT01373281?term=dengue&phase=2&fund=2&rank=4. Accessed April 3, 2014.

[2] MR Capeding et al. Clinical efficacy and safety of a novel tetravalent dengue vaccine in healthy children in Asia: a phase 3, randomised, observer-masked, placebo-controlled trial. *The Lancet*

July 2014

CONTACT:

Global Media Relations
Alain Bernal
T. +33-(0)4-37-37-50-38
alain.bernal@sanofipasteur.com
www.sanofipasteur.com