



## PHASE III EFFICACY STUDY OF SANOFI PASTEUR'S DENGUE VACCINE CANDIDATE IN LATIN AMERICA

*THE FINAL OF TWO LANDMARK PHASE III EFFICACY STUDIES OF SANOFI  
PASTEUR'S DENGUE VACCINE CANDIDATE*

### LATIN AMERICA AND CARIBBEAN PHASE III STUDY OVERVIEW

---

- The phase III clinical study conducted in Latin America and the Caribbean was a randomized, observer-blind, placebo-controlled, multicenter trial designed to assess the efficacy and safety of Sanofi Pasteur's dengue vaccine candidate in preventing dengue disease. The study was carried out in five countries in Latin America and the Caribbean and included 20,875 children and adolescents aged from 9 – 16 years.<sup>1</sup>

### 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.<sup>1</sup>
- 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 three during the 12 month active phase of the study.<sup>1</sup>
- The safety objective was to evaluate the occurrence of serious adverse events (SAEs) including SAEs of special interest, in all subjects throughout the study period.<sup>1</sup>

### STUDY METHODOLOGY

---

- 20,875 children aged between 9 and 16 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.<sup>1</sup>
  - Individuals with congenital or acquired immunodeficiency and those receiving immunotherapy or other vaccines were not eligible to take part in the study.<sup>1</sup>



- 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.<sup>1</sup>
- A program of regular contact with volunteers and school based surveillance was implemented to ensure that as many potential cases of symptomatic dengue were identified as possible during the active phase. In addition, every child with an acute febrile illness (defined as temperature  $\geq 38^{\circ}\text{C}$  on at least 2 consecutive days) was assessed and dengue fever virologically confirmed.<sup>2</sup>

## STUDY LOCATION

---

- This phase III study was conducted in 22 sites across endemic areas of Brazil (5 sites), Colombia (9 sites), Honduras (1 site), Mexico (5 sites) and Puerto Rico (2 sites).<sup>1</sup>
  - Brazil (Fortaleza, Vitória, Goiania, Campo Grande, Natal)
  - Colombia (Aguazul, Yopal, Girardot, Acacias, Armenia, Calarcá, La Tebaida, Montenegro, Bucaramanga)
  - Honduras (Tegucigalpa)
  - Mexico (Temixco, Municipio de Cd. Mante, Veracruz Puerto, Tizimin, Valladolid)
  - Puerto Rico (Guayama, San Juan)

## KEY DATES

---

- Start date (first vaccination first subject): June 2011
- Last vaccination of last subject: April 2013 (3<sup>rd</sup> dose)
- Long-term follow-up with all volunteers will continue for five years after the completion of vaccination.<sup>1</sup>

## References

---

<sup>1</sup> ClinicalTrials.gov. Study of a Novel Tetravalent Dengue Vaccine in Healthy Children and Adolescents Aged 9 to 16 Years in Latin America. Available at: <https://clinicaltrials.gov/ct2/show/NCT01374516?term=CYD15&rank=1>. Accessed July 22, 2014.

<sup>2</sup> Data on file. World Health Organization (WHO). Dengue guidelines for diagnosis, treatment, prevention and control. Available at: <http://www.who.int/tdr/publications/documents/dengue-diagnosis.pdf>. Published 2009. Accessed September, 2014.

September 2014

---

## CONTACT:

### Global Media Relations

Alain Bernal

T. +33-(0)4-37-37-50-38

[alain.bernal@sanofipasteur.com](mailto:alain.bernal@sanofipasteur.com)

[www.sanofipasteur.com](http://www.sanofipasteur.com)