Statement by the Dengue Vaccine Initiative on Sanofi Pasteur’s Phase 3 Trial Results of Dengue Vaccine Candidate

JULY 11, 2014 – Sanofi Pasteur, the vaccines division of the French pharmaceutical company Sanofi, recently published in The Lancet the results of the Phase 3 trial of its dengue vaccine candidate (CYD-TDV) conducted in Indonesia, Malaysia, the Philippines, Thailand and Vietnam.

The trial showed moderate efficacy of 57 percent against any virologically-confirmed dengue. Results show that efficacy against serotypes 1, 2, 3 and 4 is 50 percent, 35 percent, 78 percent and 75 percent, respectively. Vaccine efficacy was statistically significant for all serotypes except serotype 2. The reason behind variable vaccine efficacy is still unknown, inviting further in depth examination and analysis.

The efficacy against severe dengue or dengue hemorrhagic fever which leads to hospitalization was 67 percent in the age group that was studied between the ages of 2 and 14 in the five countries in Asia, which is an encouraging result. This trial also further reassures the safety of CYD-TDV in the first 12 months following the primary vaccine series, as results showed no signals of an increase in serious adverse events in the trial during the two years following the administration of vaccine.

A fuller assessment of the efficacy of the vaccine candidate will be possible with data from the ongoing Phase 3 trial in Latin America with the same vaccine, and these results will help us better understand the complexities and challenges of developing a dengue vaccine and help pave the way for further research. DVI continues to await for the results of the second pivotal efficacy trial in Latin America, which will be available at the end of 2014, as they will help complement these data from Asia and provide a wider lens of analysis for a global vaccine.

Background
This recent study follows a Phase 2b trial in Thailand which showed that the vaccine was safe, though poorly effective, reducing dengue cases by only 30 percent. Learn more here.

Currently, no cure or treatment exists for dengue. As dengue cases rise — putting nearly half of the world’s population at risk — so does the urgent need for a preventive intervention. A safe, effective and affordable dengue vaccine would represent a major advance for the control of dengue, the fastest spreading vector-borne viral disease, with an epidemic potential in the world.

- Read more about the burden of dengue here.
- To access the WHO Q&A of the results click here.