SANOFI PASTEUR

Statement on good clinical practice behind clinical evaluation of Dengvaxia® dengue vaccine

As a responsible international leader in vaccine development for the past 100 years, Sanofi Pasteur ensures the safety and efficacy of all its marketed vaccines. We also work with vaccine experts and medical doctors to run clinical investigations of vaccines in development, following international standards for the good and ethical conduct of all trials of new vaccines in humans.
This commitment to transparent and responsible development and introduction of vaccines applies also to the Dengvaxia® dengue vaccine.

Dengvaxia clinical trials conducted according to global standards

Dengvaxia was evaluated in 25 controlled clinical trials in 15 countries involving around 40,000 people. This study program included large-scale trials involving more than 30,000 people from 10 countries in Latin America and Asia where dengue is widespread.[i] These trials followed international good clinical practice rules, as well as local regulatory and ethical rules and regulations. In accordance with the WHO guidance for all dengue vaccine candidates, Sanofi Pasteur is also following the vaccine's long-term safety for 6 years post the first vaccination.[ii]

Safety of all trial participants monitored by independent safety board

All participants are informed and updated on the potential benefits and potential risks associated with taking part in a clinical trial. Full informed consent must be given by all participants or their parents and new information on the vaccine's safety is shared immediately with them. All trial activities are conducted under guidance of local ethics committees comprised of members of the communities where the trials were conducted.
In addition, an independent monitoring committee of scientists and clinicians, with no commercial interest in the vaccine, is in place for the dengue vaccine trials to ensure the safety of the trial participants throughout the entire clinical program.

Global regulatory oversight of Dengvaxia clinical trials

The trial design and clinical endpoints for both efficacy and safety of the dengue vaccine were reviewed by regulators in all the countries where investigations were conducted, including the US Food and Drug Administration.
During the course of the studies, Regulatory Authorities from several countries, including the European Union and the Philippine regulatory authority, made independent reviews of the studies conduct, confirming the respect of international and local standards, as well as data integrity.

Long-term safety data on Dengvaxia reported regularly

Sanofi Pasteur must provide periodic reports on adverse events in the ongoing studies and in the post-marketing use of the vaccine to country regulators. We also continue to share all data from the trials and post-marketing use of the vaccine at scientific meetings, in peer-reviewed publications and with international recommending bodies like the WHO.
In the interests of complete transparency and to inform decision making between individuals and their healthcare providers on the potential benefits and potential risks of dengue vaccination, Sanofi Pasteur issued a global statement on new long-term data on the vaccine on 29th November 2017.
The new results show an increased risk of a rare event, occurring in a minority of the population in high dengue endemic countries but a significant benefit to the majority of the population. Therefore, in the highly endemic countries that have used the vaccine, including the Philippines, the net impact of vaccination would still result in fewer hospitalizations and episodes of severe dengue.

No deaths in vaccinated children have been reported as related to the vaccine in any county where the vaccine is in use today. Meanwhile, the pain and suffering of dengue continues to be experienced by thousands of unvaccinated people in the Philippines and in other endemic parts of the world every year.
The potential for dengue vaccination to significantly reduce disease burden in the Philippines remains true and is not changed by the new finding on the vaccine.

Trial investigators bring clinical practice experience in dengue management

The achievement of making dengue a vaccine preventable disease for most people living in high endemic settings is thanks to the 40,000 people who participated in the clinical trials of the vaccine and the clinical investigators who gave their time, dedication and dengue expertise to diligently follow and evaluate the vaccine's safety and efficacy through years of clinical evaluation and ongoing long-term evaluation of the vaccine. These investigators agree to comply with all the international safety reporting requirements and data disclosure rules governing the conduct of trials involving humans.

[i] http://www.nejm.org/doi/full/10.1056/NEJMoa1506223#t=article
[ii] Limkittikul, Kriengsak, et al. Long-term (6-year) follow-up in Thai children from phase IIb proof of concept efficacy study of cyd-tdv dengue vaccine. Presentation at ACPID, Bangkok, Thailand, 7 – 10 November 2016.