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Inviragen DENVax dengue vaccine shows promise

28 February 2013 | News | By BioSpectrum Bureau

Singapore: Inviragen initiated second stage of an ongoing phase II, randomized, double-blind, placebo-controlled study of DENVax, the company's investigational dengue vaccine. Inviragen is collaborating with partners worldwide to transition the vaccine from the research bench to the clinic and from the clinic to the marketplace.

An independent data and safety monitoring board (DSMB) evaluated the preliminary safety data from the first stage of the phase II trial, in which individuals in multiple age groups received either DENVax vaccine or placebo. Upon the review and the recommendation of the DSMB, Inviragen is advancing DENVax into the second stage of this clinical trial. In this second stage, DENVax will be tested for safety and immunogenicity in approximately 200 additional children aged 18 months-to-11 years.

"The completion of the first stage of this phase II study is an important milestone for Inviragen, as it represents the first comprehensive safety evaluation of the vaccine in individuals of various ages who live in dengue endemic areas," said Dr Dan Stinchcomb, CEO, Inviragen. "The DSMB determined that the first dose of the vaccine is well tolerated in adults, adolescents and children, some of whom were pre-exposed to dengue viruses."

Inviragen's DENVax vaccine, invented by researchers at the Division of Vector-Borne Diseases of the Centers for Disease Control (CDC) and Prevention, is based on an attenuated DEN-2 virus that generates long-lasting anti-dengue immune responses. CDC scientists engineered this clinically tested, weakened DEN-2 virus to express DEN-1, DEN-3 or DEN-4 structural genes. DENVax is a four-way (tetravalent) mixture of the three engineered viruses as well as the original DEN-2 strain.

Dr Gilad Gordon, Inviragen's chief medical officer, added, "In completed and on-going phase I and II studies, we have enrolled over 400 subjects in DENVax clinical trials and more than 300 have received the vaccine. Overall, DENVax has been very well tolerated with mostly mild adverse events. The second part of this phase II clinical trial will yield additional insight about the vaccine's safety and immunogenicity in children as young as 18 months and will set the stage for future vaccine efficacy studies."