



Inviragen Presents Safety and Immune Response Data from a Phase 1 Study of its Two-Dose Dengue Vaccine, DENVax

Fort Collins, CO – December 7, 2011 – Inviragen, Inc. presented results of the Phase 1 clinical trial of DENVax conducted in Colombia at the annual [American Society of Tropical Medicine and Hygiene](#) (ASTMH) meeting today. In this randomized, placebo-controlled study of 96 healthy adults, DENVax was safe and well tolerated and induced significant neutralizing antibody responses to all four dengue virus subtypes. The most frequent adverse events reported were transient local injection site reactions.

“In this Phase 1 study, [DENVax](#) generated neutralizing antibody responses to all four dengue strains in a majority of subjects after two doses separated by only three months,” noted [Dr. Jorge Osorio](#), Inviragen’s chief scientific officer. “We believe this rapid immunogenicity sets DENVax apart from other dengue vaccines in development that require three doses. We are now testing DENVax in dengue-endemic countries and in multiple age groups. Upon further clinical testing and regulatory approval, we believe our two-dose dengue vaccine will provide a meaningful benefit for the 3.6 billion individuals living in endemic regions, as well as for international travelers.”

The Inviragen Phase 1 study was conducted in Colombia in collaboration with the Program for the Study and Control of Tropical Diseases (PECET) at Universidad de Antioquia. To ensure that the study participants had not been previously exposed to dengue, the trial was conducted in Rionegro, Colombia, a high-altitude area with no *Aedes aegypti*, the mosquito responsible for transmission of dengue. The clinical trial assessed the safety and immunogenicity of two different formulations of the tetravalent DENVax vaccine delivered by either subcutaneous or intradermal injection. Two doses of DENVax or placebo were administered to healthy, dengue-naïve adults on days 0 and 90. Results demonstrate that the vaccine was well tolerated. The most common systemic reactions -- headaches, colds and nausea -- were observed at similar frequencies in the DENVax and the placebo groups. Importantly, very few fevers, rashes or other dengue-like symptoms were seen in the vaccinated participants. After two doses, DENVax induced neutralizing antibody responses to at least three of the four dengue serotypes in 89 - 100% of individuals. Based on these encouraging Phase 1 clinical results, Inviragen has initiated an international Phase 2 study designed to assess the safety and immunogenicity of DENVax in dengue-endemic regions and in both children and adults.

“The prevalence of dengue has been steadily increasing in South America. In tropical countries such as Colombia, it can have a devastating impact on public health,” commented Professor Ivan Dario Vélez, director of the PECET and principal investigator for the DENVax trial. “We are encouraged by the safety and immunogenicity profile demonstrated by DENVax in this Phase 1 trial. Moreover, we believe that the ability to offer broad protection rapidly after only two doses would be of great importance for the future uptake of a dengue vaccine in endemic countries worldwide.”

Presentation Details

Date & Time: 3:00pm ET, December 7, 2011

Oral Session: Flavivirus: Dengue - Antivirals and Vaccines

Title: "A Recombinant Live Attenuated Tetravalent Dengue Vaccine Induces Neutralizing Antibodies to All Four Dengue Viruses in Healthy Adult Volunteers"

Date & Time: December 7, 2011

Location: Poster Session D; Abstract 1327

Title: "Safety of a Recombinant Live Attenuated Tetravalent Dengue Vaccine in Healthy Adult Volunteers"

The ASTMH annual meeting draws more than 3,500 global health professionals from around the world, and features more than 1,000 scientific presentations. The meeting is being held December 4-8, 2011 in the Philadelphia Marriott Downtown, in Philadelphia, PA.

About Inviragen, Inc.

Inviragen is focused on developing vaccines to protect against infectious diseases worldwide. Inviragen's lead product candidate is a vaccine to protect against dengue fever. Inviragen is also developing vaccines to protect against hand, foot and mouth disease and Japanese encephalitis, both of which affect millions of children in Asia. Vaccines in preclinical research stages include a chikungunya vaccine, a low-cost human papilloma virus vaccine, vaccines to protect against new forms of influenza, a vaccine to protect against West Nile and a combination plague/smallpox vaccine for biodefense. Inviragen has offices in Colorado, Wisconsin and Singapore. Please see www.inviragen.com for more details.

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