



Inviragen Initiates a Phase 2 Clinical Study of DENVax, a Recombinant, Tetravalent Dengue Vaccine

- Positive Phase 1 Safety and Immunogenicity Results to be Presented at 2011 ASTMH Meeting -

FORT COLLINS, Colo. – NOVEMBER 28, 2011 – Inviragen, Inc. today announced the initiation of a Phase 2, randomized, double-blind, placebo-controlled study of [DENVax](#), the Company’s investigational dengue vaccine. The Phase 2 trial will test the safety and immunogenicity of DENVax in multiple age groups in dengue endemic countries. The initiation of this Phase 2 study follows the successful conclusion of a Phase 1 study of DENVax that was conducted in Colombia in collaboration with [PECET](#), the Program for the Study and Control of Tropical Diseases at Universidad de Antioquia. Data from this Phase 1 study demonstrate that the vaccine is safe and well-tolerated and immunogenic in dengue-naïve adults; the results will be presented at the annual meeting of the American Society of Tropical Medicine and Hygiene (ASTMH) on December 7, 2011 in Philadelphia, PA.

“Worldwide, dengue viruses infect young children as well as adults, causing devastating disease and tens of thousands of deaths every year,” said [Dr. Dan Stinchcomb](#), CEO of Inviragen. “This Phase 2 study will further assess the safety and immunogenicity of DENVax in adults as well as children in dengue endemic countries.”

The Phase 2 clinical trial will evaluate safety and immunogenicity of DENVax, administered in two doses three months apart. In the first stage of the trial, individuals will be enrolled in four age groups: adults (aged 21 and older), adolescents (aged 11 to 20 years), pre-teens (aged 6 to 10 years) and children (aged 18 months to 5 years). An independent monitoring board will assess safety of the vaccine in subjects from each group before advancing to the next younger cohort. Following complete safety measurements in all four cohorts, the study will enter its second stage, enrolling hundreds of additional children aged 18 months to 11 years to further test the safety and immunogenicity of the two-dose DENVax vaccine.

Inviragen intends to enroll individuals in Puerto Rico, Colombia, Singapore and Thailand. “We are collaborating with leading clinical researchers in three continents to test the safety and immune responses to DENVax,” commented Dr. Gilad Gordon, Inviragen’s chief medical officer. “The data from this clinical study will provide the foundation for future large-scale Phase 3 efficacy studies to determine whether DENVax protects individuals from dengue fever in endemic countries.”

About DENVax

Inviragen's DENVax vaccine, developed by researchers at the Division of Vector-Borne Diseases of the Centers for Disease Control 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 (tetraivalent) mixture of the three engineered viruses as well as the DEN-2 strain. Inviragen is collaborating with partners worldwide to transition the vaccine from the research bench to the clinic and from the clinic to the marketplace.

About Dengue Fever

More than 3.6 billion people live in countries that have frequent dengue outbreaks. The four dengue viruses (DEN-1, DEN-2, DEN-3 and DEN-4) are spread by the mosquito, *Aedes aegypti*, which is found throughout tropical and subtropical regions. According to the Pediatric Dengue Vaccine Initiative, dengue viruses cause an estimated 30 to 50 million cases of debilitating dengue fever and 2.1 million cases of severe dengue disease leading to over 20,000 deaths every year. For more information on dengue fever, please refer to the [CDC](#) and [WHO](#) websites.

About Inviragen, Inc.

[Inviragen](#) is focused on developing vaccines to protect against infectious diseases worldwide. The Company is currently conducting Phase 1 and Phase 2 studies of DENVax, a vaccine to protect against dengue fever, as well as a Phase 1 clinical trial of its vaccine against hand, foot and mouth disease (HFMD). Vaccines to protect against chikungunya and Japanese encephalitis, which affect millions of individuals in Asia, are in earlier stages of clinical manufacturing and development. Inviragen is also pursuing preclinical research and development of a low-cost human papilloma virus vaccine, vaccines to protect against new forms of influenza and a combination plague/smallpox vaccine for biodefense. Inviragen has offices in Colorado, Wisconsin and Singapore. See www.inviragen.com for more details.

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