



Inviragen Advances DENVax into Second Stage of Ongoing Phase 2 Clinical Study

FORT COLLINS, Colo. – FEBRUARY 27, 2013 – Inviragen, Inc. today announced the initiation of the second stage of an ongoing Phase 2, randomized, double-blind, placebo-controlled study of [DENVax™](#), the Company's investigational dengue vaccine. An independent data and safety monitoring board (DSMB) evaluated the preliminary safety data from the first stage of the Phase 2 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 2 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 of 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."

[Dr. Gilad Gordon](#), Inviragen's chief medical officer added, "In completed and on-going Phase 1 and 2 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 2 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."

Study Details

The Phase 2 study is enrolling individuals in Puerto Rico, Colombia, Singapore and Thailand. The first stage evaluated the safety and immunogenicity of two doses of DENVax, administered three months apart. Approximately 150 individuals were enrolled in this first stage in four different age groups: adults (aged 21 and older), adolescents (aged 11 to 20 years), school-age children (aged 6 to 10 years) and pre-school children (aged 18 months to 5 years). Following the assessment of an independent monitoring board, the study was designed to enter its second stage, in which it will enroll approximately 200 children aged 18 months to 11 years to further test the safety and immunogenicity of the two-dose DENVax vaccine. It is expected that the full results of the first stage of the Phase 2 study will be presented at an appropriate meeting later this year.

About DENVax

Inviragen's DENVax vaccine, invented 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 original 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 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 DVI, [CDC](#) and [WHO](#) websites.

About Inviragen, Inc.

Inviragen is focused on developing vaccines to protect against infectious diseases worldwide. Inviragen's vaccine to protect against dengue fever is in Phase 2 clinical testing. A vaccine designed to protect children from hand, foot and mouth disease has completed Phase 1 clinical testing. Vaccines to protect against chikungunya and Japanese encephalitis, which affect millions of individuals in Asia, are in development. Vaccines in preclinical research stages include a second generation human papilloma virus vaccine, vaccines to protect against new forms of influenza and a combination plague/smallpox vaccine for biodefense. Founded in 2005 with offices in Colorado, Wisconsin and Singapore, Inviragen's investors include Charter Life Sciences (Palo Alto, CA), Venture Investors (Madison, WI), Bio*One Capital Pte. Ltd. (Singapore) and Phillip Private Equity (Singapore). See www.inviragen.com for more details.

Enquires may be directed to:

Media Contact:

Aline Schimmel
312-238-8957
aschimmel@scientapr.com

Contact at Inviragen:

Dr. Dan Stinchcomb
970-372-4754
dstinchcomb@inviragen.com