



## **Inviragen's Dengue Vaccine to Begin Clinical Testing**

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**Fort Collins, Colorado**

Inviragen has announced the initiation of the first clinical trial of its vaccine to protect against dengue fever. The trial, to be conducted at Saint Louis University, is designed to assess the safety of Inviragen's investigational dengue vaccine.

"Initiating this first clinical study of DENVax™ is an important milestone for Inviragen," commented Dr. Dan Stinchcomb, the company's Chief Executive Officer. "The transition of this vaccine from the bench to the clinic is the culmination of many years of work by Inviragen, scientists at the Centers for Disease Control and Prevention (CDC) and our international collaborators."

Inviragen's DENVax investigational vaccine, developed by researchers at the CDC's Division of Vector-Borne Diseases, 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 mixture of the three engineered viruses and the original DEN-2 strain. Inviragen completed preclinical testing, formulation, and manufacturing of the tetravalent DENVax vaccine to be used in the upcoming clinical trials.

"In animal model studies, DENVax is safe, induces neutralizing antibodies to all four dengue serotypes and protects against dengue infection," noted Dr. Jorge Osorio, Inviragen's Chief Scientific Officer. "An Investigational New Drug application (IND) has been filed and reviewed by the Food and Drug Administration (FDA). We look forward to testing the safety and immunogenicity of the vaccine in the Phase 1 trial conducted at Saint Louis University."

Saint Louis University is one of the Vaccine and Treatment Evaluation Units funded by the National Institute of Allergy and Infectious Diseases (NIAID), which is part of the National Institutes of Health. For the clinical study, 72 healthy adult volunteers will receive injections of a placebo, a lower dose or a higher dose of the investigational vaccine. The

vaccine will be administered in two doses, three months apart, either between the layers of the skin as an “intradermal” shot or under the skin as a “subcutaneous” injection.

“Finding a safe and effective vaccine for dengue is a global health priority,” said Sarah George, M.D., assistant professor in the division of infectious diseases at Saint Louis University and principal investigator of the study. “Approximately 3.6 billion people worldwide – more than half of the world’s population – now are at risk of contracting dengue disease.”

Thirty-six million cases of dengue fever are thought to occur per year worldwide. The most severe form of the disease, dengue hemorrhagic fever, leads to the death of approximately 20,000 people annually worldwide. Both the number of reported cases and the number of countries affected have been on the rise, and the disease could continue to spread because of increasing urbanization, international travel and global warming. Dengue is a major risk for international travelers: dengue cases among travelers outnumber malaria cases in every continent except Africa.

In addition to the clinical trial in the U.S., Inviragen anticipates performing additional human clinical testing of DENVax in Colombia and Singapore.

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### **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](http://www.inviragen.com) for more details.

### **About Saint Louis University**

Established in 1836, Saint Louis University School of Medicine has the distinction of awarding the first medical degree west of the Mississippi River. The school educates physicians and biomedical scientists, conducts medical research, and provides health

care on a local, national and international level. Research at the school seeks new cures and treatments in five key areas: cancer, infectious disease, liver disease, aging and brain disease and heart/lung disease.