June 16, 2011 01:00 UTC

Inviragen Initiates Phase 1 Study of Hand, Foot and Mouth Disease Vaccine in Singapore

SINGAPORE--(BUSINESS WIRE)-- Inviragen announced today the initiation of the first clinical trial of the Company's proprietary Hand, Foot and Mouth Disease (HFMD) investigational vaccine, INV21, a highly purified virus particle preparation designed to protect against HFMD caused by enterovirus 71 (EV71). The study will be conducted in Singapore at the Investigational Medicine Unit at the National University Health System under Inviragen's memorandum of understanding with the Duke-NUS Graduate Medical School. This Phase 1 clinical trial of INV21 will assess the safety of the vaccine as well as immune responses in healthy adult volunteers.

"This first clinical study of INV21 is the result of years of research by Inviragen's scientists, and is an important milestone for our company," commented Dr. Joseph Santangelo, Inviragen's chief operating officer. "INV21 was developed in Singapore by Inviragen and our preclinical studies have demonstrated that this vaccine induces broad, neutralizing antibodies to multiple EV71 isolates. Duke-NUS and their strong ties to the hospital community have sped the advance of INV21 into human clinical testing."

"We are committed to translating basic science into clinical practice with the ultimate goal of bringing vaccines such as INV21 to market for the benefit of people in Singapore and the world," stated the clinical trial principal investigator Dr. Paul Tambyah, associate professor of the Department of Medicine, Yong Loo Lin School of Medicine, National University Singapore and senior consultant, Division of Infectious Diseases at the National University Hospital, Singapore. "HFMD can be severely debilitating for some children with a risk of paralysis and death. It also remains an ongoing public health threat with significant economic impact as it continues to affect young children in Singapore and the region. We are eager to continue to work with Inviragen to advance the development of INV21, as well as other vaccine candidates."

The trial is a placebo controlled randomized clinical study and will enroll healthy adults, aged 21 to 45 years. Each individual will receive two immunizations separated by four weeks and will be monitored for any adverse reactions after each administration. Immune responses to INV21 will be measured one, two and six months after the second immunization.

About Hand, Foot and Mouth Disease (HFMD)

HFMD is a disease common in children throughout the world. However, the disease is endemic in the Asia Pacific where its incidence has been increasing steadily over the past two decades. Although the disease is typically of short duration, there has been an increase in severe HFMD cases, including central nervous system involvement, associated with EV71. HFMD epidemics have been reported in most Asian countries, particularly Singapore, Taiwan, Malaysia, Vietnam, Korea, Hong Kong and China. Recent reports from the Chinese

Ministry of Health revealed more than 1.7 million HFMD infections resulting in 876 deaths from 1 January to 30 November 2010; there were 1.1 million infections with 353 deaths reported for the previous year. In 2010, 30,878 HFMD infections were reported in Singapore, an island nation with a population of approximately five million people, of which roughly 200,000 fall into the most susceptible age group of one-to-five years. No vaccines currently exist for HFMD.

About Inviragen, Inc.

Inviragen is focused on developing vaccines to protect against infectious diseases worldwide. Inviragen's vaccines to protect against dengue fever and HFMD are in Phase 1 clinical testing. Vaccines to protect against chikungunya and Japanese encephalitis which affect millions of individuals in Asia, are in clinical manufacturing and development. Vaccines in preclinical research stages include 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.

About Duke-NUS Graduate Medical School Singapore

The Duke - NUS Graduate Medical School Singapore (Duke - NUS) was established in 2005 as a strategic collaboration between the Duke University School of Medicine, located in N. Carolina, USA and the National University of Singapore (NUS). Duke - NUS offers a graduate entry, 4 - year M.D. (Doctor of Medicine) training programme based on the unique Duke model of education, with one year dedicated to independent study and research projects of a basic science or clinical nature. The first batch of students will graduate in 2011. Duke - NUS also offers M.D./PhD and PhD programmes. As a player in Singapore's biomedical community, Duke - NUS has identified five Signature Research Programmes: Cancer & Stem Cell Biology, Neuroscience and Behavioral Disorders, Emerging Infectious Diseases, Cardiovascular & Metabolic Disorders, and Health Services and Systems Research. For more information, please visit www.duke-nus.edu.sg