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Inviragen Hand, Foot and Mouth Disease Vaccine Generates Immune Responses in 100% of Study Participants

SINGAPORE--([BUSINESS WIRE](#))-- [Inviragen](#) today reported top-line results of a placebo-controlled, randomized Phase 1 trial of INV21, the Company's highly purified virus particle vaccine against [Hand, Foot and Mouth Disease](#) (HFMD) caused by enterovirus 71 (EV71). In the clinical study, healthy adults received two immunizations each of either a high- or low-dose formulation of INV21. Study participants were monitored for safety and for immune response after each administration. Antibodies that neutralize the EV71 virus were measured in individuals who received both doses of the vaccine. One hundred percent of individuals who received the vaccine had significantly increased EV71 immune responses after immunization, which may signify protection against infection. Further, INV21 was safe and well tolerated in this population. Inviragen expects to present complete safety and immunogenicity data at an appropriate infectious disease meeting in 2012.

"Hand, foot and mouth disease is a significant public health problem in East Asia including Singapore. The development of vaccine candidates such as INV21 is a positive result of the strong collaboration between Singapore academic clinicians and local industry partners in addressing emerging infectious diseases threats," said clinical trial principal investigator [Dr. Paul Tambyah](#). "The results of this first INV21 clinical trial are very promising. We look forward to continued collaboration on HFMD research and carrying out large scale trials in partnership with Inviragen to bring successful vaccine candidates such as INV21 closer to clinical use to help protect vulnerable children in this part of the world." Dr. Tambyah is 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.

HFMD has taken a significant toll across South East Asia, affecting approximately two million children every year, with severely debilitating and sometimes fatal consequence. Many countries are implementing extra preventative measures in an attempt to control the outbreak. In recent weeks, the number of HFMD cases in Singapore has risen past the epidemic threshold, as defined by the Ministry of Health. In the first nine weeks of 2012, there were 5,568 cases of HFMD, compared to 1,908 during the same period last year. During the first two months of 2012, over 7,700 children in Vietnam contracted HFMD with nine deaths. In 2011, more than 110,000 Vietnamese contracted HFMD and 166 children subsequently died. Malaysia has also seen a recent surge. As of 6 March, the state of Sarawak reported a total of 2,143 cases with 35 pre-school/school and child care centers being served with closure orders in an effort to break the cycle of transmission.

"We were able to initiate this study rapidly and complete it in only six months through a productive relationship with the Singapore National University Health System (NUHS) and our collaboration with Duke-NUS Graduate Medical

School,” commented [Dr. Joseph Santangelo](#), Inviragen’s chief operating officer. “Our two-dose INV21 vaccine induced neutralizing antibody responses in all of the immunized adults in this Phase 1 trial and we look forward to exploring the vaccine’s safety and immunogenicity in children in future clinical trials later this year.”

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 infections with sequelae which include neurological symptoms such as meningitis, encephalitis and polio-like paralysis. In 2011 there was an increase in the number of cases of HFMD in East and South East Asia. Recent reports reveal more than two million [HFMD infections in 2011](#). No vaccines or therapeutic modalities currently exist for HFMD.

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. Inviragen has offices in Colorado, Wisconsin and Singapore. See www.inviragen.com for more details.

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