Inviragen Aims to Continue Development of INV21

An Inactivated Vaccine Candidate for the Prevention of Hand, Foot and Mouth Disease caused by Enterovirus 71

Dr Joseph Santangelo
Chief Operating Officer
Inviragen, Inc.

Hand, Foot and Mouth Disease (HFMD) is caused by enteroviral pathogens such as enterovirus 71 (EV71). Although this is generally a self-limiting disease characterised by fever, mouth ulcers, and a rash, HFMD caused by EV71 can lead to viral meningo-encephalitis, myocarditis or poliomyelitis-like paralysis, and may be fatal.

EV71 and HFMD are endemic in Asia, causing significant morbidity, mortality and economic impact in recent years. INV21 is a purified, inactivated EV71, alum-formulated vaccine, developed for the prevention of HFMD caused by EV71. Inviragen recently completed a Phase 1 clinical trial of INV21 in Singapore with Dr Paul Tambyah of the National University Hospital as the Principal Investigator.

Thirty-six healthy males and females aged 21 to 45 years were enrolled into a randomised, double-blind, placebo-controlled study at the Investigational Medicine Unit, National University Hospital, Singapore. Subjects were enrolled to either Low Dose [12 on INV21 (0.6 μg EV71/dose); 6 on placebo] or High Dose [12 on INV21 (3 μg EV71/dose); 6 on placebo] group. Subjects received two injections (Day 0, Day 28) intramuscularly, and were followed for safety and immunogenicity assessments through Day 56.

35/36 subjects completed the study through Day 56. Most common adverse events in INV21 and placebo subjects (cough: 5/36 subjects; rhinorrhea: 5/36 subjects; pyrexia: 4/36 subjects; influenza: 3/36 subjects) were mild and time-resolved. Minimal reactions were observed at the injection site, with similar profiles seen at both dose levels.

Mild (Grade 1) pain, tenderness and pruritis were reported in 1 subject in each treatment group. Grade 1 erythema and induration were reported in 1 subject in High Dose group. No clinically significant changes in chemistry, haematology and urinalysis parameters were observed in either group.

Highest EV71-neutralising antibody titres were detected 2 weeks post second dose (Day 42), with all subjects seroconverting (≥ 4-fold rise in titre compared to baseline) at this time point (Low Dose GMT = 323; High Dose GMT = 452). Long term assessments through Day 196 are now complete and the immune responses continue to be positive.

This "first-in-man" trial demonstrated that INV21 is a safe and immunogenic vaccine candidate for the prevention of HFMD caused by EV71. An appropriate team of clinical investigators is now being organised to conduct a Phase 2 clinical trial in Singapore. The planned Phase 2 clinical trials are needed to address the ongoing regional HFMD epidemic, and ultimately reduce mortality and morbidity due to EV71 infection. INV21 was developed in Singapore by local researchers and Inviragen desires to continue this clinical program in Singapore.

It is hoped that INV21 will be a successful product to meet an unmet clinical need not only in Singapore, but also more widely in Asia. Development of vaccine candidates like INV21 is part of the industry's efforts to address this growing problem of HFMD infections in Asia. Inviragen is focused on developing vaccines to protect against infectious diseases worldwide.

Founded in 2005 with offices in Singapore, Colorado and Wisconsin, Inviragen's investors include EDBI subsidiary Bio*One Capital Pte. Ltd. (Singapore), Phillip Private Equity (Singapore), Charter Life Sciences (Palo Alto, CA) and Venture Investors (Madison, WI).

See www.inviragen.com for more details.