

Sinovac makes progress in EV71 clinical trial

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Singapore: Sinovac Biotech, a leading provider of biopharmaceutical products in China, is conducting double-blinded, randomized, placebo controlled Phase III trial for its proprietary inactivated Enterovirus 71 (EV71) vaccine against hand, foot and mouth disease (HFMD) at three sites across China's Jiangsu province.

This study is designed to demonstrate the efficacy of the EV71 vaccine in the prevention of the diseases caused by EV71 in infants 6 to 35 months old. About 10,000 healthy infants completed the vaccination schedule in the first quarter of 2012, prior to the epidemic season for HFMD in China. The disease surveillance period began 28 days after completion of the two-dose regimen.

A three arm active surveillance system, comprised of village health clinics, township hospitals, and local county Centers for Disease Control and Prevention (CDC), has been established at each clinical site and is in charge of epidemic surveillance, case diagnosis, epidemiological survey, and sample collection.

A number of patients with HFMD symptoms have been identified EV71 positive. All professionals in the surveillance system are actively monitoring the epidemic situation to try to achieve the clinical target in advance.

"The current HFMD epidemic situation is one of the most serious in the past five years, with a nearly 110 percent increase in reported cases between January 2012 and May 2012, and with almost twice the number of fatalities," said Dr. Weidong Yin, Chairman and CEO. "There are no specific treatments for EV71 and no effective prevention methods, and we are continually reminded of the importance of rapidly developing a high quality vaccine against EV71. By simultaneously conducting the EV71 vaccine Phase III trial, maintaining ongoing discussions with the SFDA, and preparing our dedicated production facility, we intend to address this unmet need by being well positioned to provide this vaccine to our children soon after the vaccine is approved. We are on track to complete Phase III of the trial before the middle of next year."