BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Sinovac reports positive results from EV71 trial

15 March 2013 | News | By BioSpectrum Bureau

Singapore: Sinovac Biotech, a provider of vaccines in China, reported preliminary top-line data from its phase III clinical trial assessing the efficacy, immunogenicity and safety of the company's proprietary Enterovirus 71 (EV71) vaccine against hand, foot and mouth disease.

The primary objective of the study was to evaluate the efficacy of the EV71 vaccine in the prevention of hand, foot and mouth disease caused by EV71 in infants of six to 35 months old. The preliminary phase III data showed that Sinovac's EV71 vaccine was 95.4 percent efficacious against the disease.

The phase III trial showed good immunogenicity and safety for Sinovac's EV71 vaccine. The overall incidence of serious adverse events in this trial was 2.2 percent among the EV71 candidate vaccine recipients and 2.6 percent among those receiving a control vaccine during the fourteen months observation period. The difference in rates of serious adverse events is not statistically significant. Most of them were considered unlikely to be vaccine-related.

The double-blinded, randomized, placebo controlled phase III clinical trial was conducted at three sites across China's Jiangsu province. Approximately 10,000 healthy infants completed the two dose vaccination schedule (at 0 and 28 days) in the first quarter of 2012, prior to the hand, foot and mouth disease epidemic season in China, followed by active monitoring period.

In parallel, Sinovac conducted another clinical study that was comprised 1,400 volunteers and designed to evaluate the consistency of three consecutive lots of EV71 vaccine manufactured by the company. The study results showed consistent immune response for all three lots and a good safety profile. With immunogenicity equivalent across the three consecutive lots, the results showed Sinovac's vaccine production process and quality are stable.

In March 2008, an EV71 outbreak in Fuyang City of China's Anhui Province caused 23 fatalities, and attracted significant attention from the government and medical communities. In May 2008, the PRC Ministry of Health identified EV71 as a Class

C infectious disease, according to prevention and control regulations. EV71 outbreaks have increased over the last five years, with over one million cases identified and 500 to 900 reported fatalities each year.

Dr Weidong Yin, chairman, president and CEO of Sinovac, commented, "We are excited to report an over 95 percent efficacy rate from the Phase III trial on our proprietary EV71 vaccine candidate. The conclusion of this trial marks an important milestone in the development of our proprietary vaccine. Hand, foot, and mouth disease continues to represent a significant unmet public health need and economic burden in China, as well as several other Asian countries. Our EV71 vaccine is poised to provide an effective solution to prevent hand, food and mouth disease caused by EV71, a much needed resource given the current limited prevention and EV71 specific treatment methods. At Sinovac, we are committed to our stated mission to develop and supply vaccines to eliminate human diseases."

Professor Hua Wang, lead principal investigator, stated, "The phase III study for Sinovac's EV71 vaccine candidate met its primary objective. The trial results demonstrated that the vaccine is not only safe, but shows significant efficacy in subjects."

The company's next step is to finalize the clinical report, which will become an important part of documents to be filed with the PRC State Food and Drug Administration for the application of new drug certificate, GMP certification, and the production license in order to commence the commercial production of the vaccine. In parallel, Sinovac's dedicated EV71 vaccine manufacturing facility has been completed and is ready for the GMP inspection by the SFDA.

Sinovac obtained clinical research approval for its proprietary EV71 vaccine candidate from the SFDA in December 2010, and completed phase I and II clinical trials in 2011. The preliminary results of the phase I and phase II studies confirmed that Sinovac's vaccine candidate has good safety and immunogenicity profile.