BioSpectrum the business of Bio & Health Sciences ASIA EDITION

China SFDA acknowledges Sinovac phase III trial sites

June 12, 2012 | Regulatory | By BioSpectrum Bureau

China SFDA acknowledges Sinovac phase III trial sites



Singapore: Sinovac Biotech revealed that the SFDA expert, who inspected the three phase III study sites of its proprietary inactivated Enterovirus 71 (EV71) vaccine against hand, foot and mouth disease (HFMD), positively acknowledged the comprehensive surveillance work performed by the sites.

In May 2012, an expert from the Center for Drug Evaluation within the State Food and Drug Administration (SFDA) completed an inspection of the three phase III study sites in Jiangsu Province, as well as the central laboratories set up by the Chinese Center for Disease Control and Prevention (CDC), according to the good clinical practice (GCP) guidelines.

As part of the inspection, study investigators from the three sites presented reports on the site's procedures of vaccination, safety monitoring and case surveillance, and the EV71 epidemic situation. The inspector also assessed the management systems at the three central laboratories and their compliance with standard operating procedures.

After the inspection, the SFDA expert positively acknowledged the comprehensive surveillance work performed by the clinical sites, and confirmed its importance to the clinical evaluation of the EV71 vaccine. Additionally, the SFDA expert indicated that the site inspection would facilitate further interaction between the SFDA and the investigators to solve any problems or issues that may arise during the study period, which will be beneficial as the Company advances through the regulatory process.

Dr Weidong Yin, chairman, president and CEO, said, "With no specific treatments for EV71 and no effective prevention methods, we are continually reminded of the importance of rapidly developing a high quality vaccine against Enterovirus71. 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 it is approved. We remain on track to complete Phase III of the trial before the middle of next year."