BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Sinovac Announces Preliminary Results of Phase III Trial on sIPV

19 April 2018 | News

The trial commenced in August 2017 with twelve hundred healthy volunteer subjects enrolled in the study

Sinovac Biotech, a leading provider of biopharmaceutical products in China, has announced preliminary results of a phase III clinical study on Sabin inactivated polio vaccine ("sIPV") developed by Sinovac Biotech on the unblinding conference held on April 19, 2018.

The preliminary results of the trial after unblinding show the seroconversion rate of poliovirus type II is superior to the control vaccine and seroconversion rates of the other two types of poliovirus are non-inferior to the control vaccine. And geometric mean titer ("GMT") of three poliovirus types are all higher than the control vaccine. The Company will prepare the production license application after the clinical report is finalized.

The phase III trial is a randomized, double-blind, controlled clinical trial to evaluate the immunogenicity and safety of sIPV in 2-month-old infants. The trial commenced in August 2017 with twelve hundred healthy volunteer subjects enrolled in the study. The primary vaccination schedule sets three doses with a one month interval between doses and the trial was carried out in Jiangsu province, China.

Mr. Weidong Yin, Chairman, President and CEO of Sinovac, commented, “The promising results from the phase III clinical trial are an important milestone we achieved towards providing vaccines to eliminate human disease related to polio. The Company will commercialize this vaccine in the China market as well as the markets in which the United Nations (“UN”) operates under the WHO’s Polio Eradication & Endgame Strategic Plan. The vaccine will also contribute to the diversification of our pipeline product portfolio by providing us with the opportunity to develop a sIPV related combo vaccine in the future.”

Sinovac has entered into a license agreement with Intravacc (Institute for Translational Vaccinology) from Netherlands to develop and commercialize sIPV for distribution to China and other countries. According to the agreement, Sinovac has committed to commercializing the vaccine in China, inclusive of conducting clinical trials, obtaining regulatory approval, and launching the sIPV. The Company obtained the clinical license of sIPV in December 2015. The phase I and phase II trials were completed in 2017.