BioSpectrum the business of Bio & Health Sciences ASIA EDITION

FDA designates Chugai's bispecific antibody as breakthrough therapy

14 September 2015 | News | By BioSpectrum Bureau

FDA designates Chugai's bispecific antibody as breakthrough therapy

Japan's pharma giant, Chugai Pharmaceutical Co. has reported that the US Food and Drug Administration (FDA) has granted the breakthrough therapy designation to 'ACE910' for the prophylactic treatment of people who are 12 years or older with hemophilia A with factor VIII inhibitors.

In the release, the company indicated that ACE910 is a bispecific antibody created using its proprietary antibody engineering technologies for the purpose of mimicking the function of blood coagulation factor VIII, in order to provide a novel concept for the treatment of hemophilia A. The Japanese phase I/II clinical study is currently being conducted to investigate the safety and exploratory prophylactic efficacy of ACE910 for preventing bleeding with the once-weekly subcutaneous injection of ACE910 in patients both with and without inhibitors.

Chugai said that the breakthrough therapy designation was adopted as part of the FDA Safety and Innovation Act (FDASIA) enacted in July 2012 aiming at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms.

The designation for ACE910 was based on the domestic phase I / II clinical study conducted with Japanese and Caucasian healthy volunteers as well as well as Japanese hemophilia A patients. It is the third such designation for a drug candidate developed by Chugai after alectinib (for patients with ALK- positive non-small cell lung cancer whose disease progressed on crizotinib therapy) and tocilizumab (systemic sclerosis).

Development rights for regions other than Japan, Taiwan, and Korea were licensed out to F. Hoffman-La Roche Ltd. Chugai and Roche plan to initiate a phase III global study in patients with inhibitors by the end of 2015 and a phase III global study in patients without inhibitors in 2016. Additionally, a trial in pediatric patients with hemophilia A is planned to commence in 2016.