

CFDA accepts WuXi MedImmune's novel anti-IL6 monoclonal antibody IND application for review

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WuXi PharmaTech (Cayman) Inc. (NYSE: WX), a leading open-access R&D capability and technology platform company serving the global pharmaceutical, biotechnology, and medical device industries, announced today that an Investigational New Drug (IND) application for WuXi MedImmune's novel anti-IL6 monoclonal antibody for rheumatoid arthritis has been accepted for review by the China Food and Drug Administration (CFDA).

In September 2012, MedImmune, the global biologics research and development arm of AstraZeneca, and WuXi AppTec formed the joint venture WuXi MedImmune Biopharmaceutical Co. Limited to develop and commercialize MEDI5117, a novel, investigational, long-acting monoclonal antibody for autoimmune and inflammatory diseases, the first such collaboration in China between a global company and a Chinese company to develop novel biologics. WuXi AppTec completed all CMC, nonclinical, and clinical sections of the dossier, and the wholly owned subsidiary of the joint venture filed an IND for it with the Jiangsu provincial FDA as a Class 1 therapeutic biologic in December 2014. WuXi AppTec's biologics and pre-clinical facilities in Shanghai, Suzhou, and Wuxi passed the Jiangsu FDA's onsite inspections in January 2015. The IND application has now been entered into the system of the CFDA for technical review. WuXi AppTec will continue to provide manufacturing for the program at its state-of-the-art biologics facilities, the first in China to meet cGMP standards of the United States, the European Union, and China, as well as provide local regulatory, pre-clinical, and clinical trial support.

"We are very pleased that our collaboration with MedImmune has advanced this important novel class 1 biologic on schedule," said Dr. Ge Li, Chairman and CEO of WuXi PharmaTech. "WuXi's capabilities in integrated biologics discovery, development, and manufacturing offer a global platform with the highest quality standards. This initiative showcases WuXi's capabilities as a gateway for developing novel biologics in China."

Source:

WuXi PharmaTech (Cayman) Inc.
