



[For Immediate Release]



The U.S. FDA Completed Pre-License Inspection (PLI) of WuXi Biologics cGMP Manufacturing Facilities for Production of TMB-355 (Ibalizumab)

(Hong Kong, 3 Aug 2017) – **WuXi Biologics (2269.HK)**, a global leading open-access biologics technology platform company offering end-to-end solutions for biologics discovery, development and manufacturing, and its partner TaiMed Biologics (4147.TWO) today announced that the U.S. Food and Drug Administration (U.S. FDA) has completed the Pre-License Inspection (PLI) of WuXi Biologics cGMP manufacturing facilities for production of TMB-355 (Ibalizumab) with no critical findings. The 5-inspector 13-day inspection covered both drug substance and drug product facilities in the city of Wuxi, China. WuXi Biologics is expected to complete all follow-up actions within three months, which should not impact the BLA review timeline of ibalizumab.

This is first such inspection in China. If ibalizumab is approved, the inspected facilities will be the first cGMP biologics manufacturing facilities in China approved by the U.S. FDA for commercial biologics products, marking yet another milestone that Wu Xi Biologics has set in China. This pending U.S. FDA approval continues to reinforce the strong commitment to quality WuXi Biologics has made to its global client base.

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About Ibalizumab

Ibalizumab is a humanized monoclonal antibody being developed for the treatment of Multiple Drug Resistant Human Immunodeficiency Virus-1 (MDR HIV-1) infection. Unlike other antiretroviral agents, ibalizumab primarily binds to the second extracellular domain of the CD4+ T cell receptor, away from major histocompatibility complex II molecule binding sites. It potentially prevents HIV from infecting CD4+ immune cells while preserving normal immunological function. Ibalizumab is active against HIV-1 resistant to all approved antiretroviral agents. US FDA designated ibalizumab as a breakthrough therapy and is currently under review following the acceptance of a Biologics License Application (BLA) in June 2017. The PDUFA date is set to Jan 3 2018.

About TaiMed Biologics

TaiMed Biologics was formed to realize the vision of creating a world-class, innovation-based biotechnology company that will satisfy the unmet medical needs of patients around the world. For more information, please visit <http://www.taimedbiologics.com>.

About WuXi Biologics

WuXi Biologics is the only open-access biologics technology platform in the world offering end-to-end solutions to empower anyone to discover, develop and manufacture biologics from concept to commercial manufacturing. Our company history and achievements demonstrate our commitment to providing a truly ONE-stop service offering and value proposition to our global clients. For more information on WuXi Biologics, please visit: <http://www.wuxibiologics.com>.

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