Prima BioMed and WuXi Biologics Announce First Dose of Chinese-Manufactured Biologic in EU Clinical Trial

Highlights

- First-Ever Chinese-Manufactured Biologic Dosed in a European Clinical Trial
- Prima BioMed Dosed First Patient in AIPAC Immuno-Oncology Trial in Metastatic Breast Cancer

SHANGHAI and SYDNEY, March 2, 2016 /PRNewswire/ -- WuXi Biologics Co. Ltd., a wholly owned subsidiary of WuXi AppTec Co. Ltd. (WuXi), and Prima BioMed Ltd. (Prima) (ASX: PRR; NASDAQ: PBMD), a leading immuno-oncology company, announced today that through their strategic supply partnership, Prima's first-in-class immuno-oncology product candidate IMP321 (LAG-3 Ig fusion protein), manufactured at WuXi's state-of-the-art cGMP facility in China, has now been dosed in a Phase IIb clinical trial in Belgium.

This event represents two significant milestones. It is the first time a biologic manufactured in China has been released for use in a clinical trial within countries in the EU. It also marks the first patient being dosed in AIPAC (Active Immunotherapy PAClitaxel), Prima's Phase IIb clinical trial in metastatic breast cancer. WuXi is supplying IMP321 to Prima's AIPAC trial, which is being conducted in Europe, as well as to its TACTI-Mel Phase I melanoma trial currently recruiting in Australia.

Belgium's Federal Agency for Medicines and Health Products approved the Clinical Trial Application (CTA) for IMP321 on October 25, 2015. The CTA was also approved in the Netherlands and is pending in several other EU countries.

"We are very pleased to work with such a distinguished team at Prima BioMed," said Dr. Chris Chen, CEO of WuXi Biologics. "With the start of this exciting clinical trial for IMP321, in addition to recent CTA filings and approvals for other product candidates of WuXi partners, WuXi Biologics is rapidly becoming a significant contributor to the expedited development of innovative biologics in the EU."

"We congratulate our partner Prima BioMed on their exciting progress," said Dr. Ge Li, Chairman and CEO of WuXi AppTec. "This milestone shows that WuXi's strong investment in an integrated discovery, development and manufacturing platform in biologics continues to enable entrepreneurs around the world to realize their dreams of bringing potentially life-saving medicines to patients faster."

Mr. Marc Voigt, CEO of Prima BioMed, added, "We have benefited greatly from the considerable expertise of the scientists and staff at WuXi in producing the material we need for our AIPAC clinical trial. The quality of the product WuXi produced and their high operating standards have been most impressive, and we are honored to be the first company to conduct a clinical trial in Europe with material produced in China."

About WuXi AppTec

WuXi AppTec is a leading open-access R&D capability and technology platform company serving the pharmaceutical, biotechnology, and medical device industries, with operations in China and the United States. As a research-driven and customer-focused company, WuXi PharmaTech provides pharmaceutical, biotechnology, and medical device companies with a broad and integrated portfolio of laboratory and manufacturing services throughout the drug and medical device R&D process. WuXi is also building a platform to provide clinical diagnostic services directly to physicians and their patients globally. WuXi AppTec's services are designed to help its global partners in shortening the cycle and lowering the cost of drug and medical device R&D. For more information on WuXi's biologics services, please visit: http://www.wuxibiologics.com.

About AIPAC (Active Immunotherapy PAClitaxel)

AIPAC is the acronym for Prima's multicentre, Phase IIb, randomised, double-blind, placebo-controlled study in hormone receptor-positive metastatic breast carcinoma patients receiving IMP321 (LAG-3 Ig fusion protein) or placebo as adjunctive to a standard chemotherapy treatment regimen of paclitaxel. The primary purpose of the AIPAC trial is to determine the clinical benefit of IMP321 in terms of Progression-Free Survival as the primary clinical endpoint in this patient population. Details of the AIPAC study will be posted on www.clinicaltrials.gov in due course.

About Prima BioMed

Prima BioMed is a globally active biotechnology company that is striving to become a leader in the development of immunotherapeutic products for the treatment of cancer. Prima BioMed is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximise value to shareholders.

Prima's current lead product is IMP321, based on the LAG-3 immune control mechanism, which plays a vital role in the regulation of the T cell immune response. IMP321, which is a soluble LAG-3 Ig fusion protein, is an APC activator boosting T cell responses for cancer chemo-immunotherapy and in other combinations and has completed early Phase II trials. A number of additional LAG-3 products, including antibodies for immune response modulation in autoimmunity and cancer, are being developed by large pharmaceutical partners.

Prima BioMed is listed on the Australian Stock Exchange and on the NASDAQ in the US. Please visit http://www.primabiomed.com.au.

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