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ASIA EDITION

WuXi PharmaTech partners with Pharmacyclics

November 19, 2013 | News | By BioSpectrum Bureau



Singapore: Shanghai SynTheAll (STA) Pharmaceutical, subsidiary of WuXi PharmaTech, a leading pharmaceutical, biotechnology and medical device research and development outsourcing company with operations in China and the United States, has entered into a supply arrangement with US based Pharmacyclics.

This follows a multiple-year development and clinical manufacturing partnership that supported Pharmacyclics with the expedited New Drug Application submission and final approval by USFDA. After an expedited review by the FDA, IMBRUVICA received approval on November 13, 2013, for treatment of patients with mantle cell lymphoma who have received at least one prior therapy. This indication is based on overall response rate. An improvement in survival or disease-related symptoms has not been established. In the GMP pre-approval inspection of WuXi's manufacturing facilities in August, no Form 483 observations were issued by the FDA.

IMBRUVICA is a first-in-class, oral therapy and is a new agent that inhibits a protein called Bruton's tyrosine kinase (BTK). BTK is a key signaling molecule of the B-cell receptor signaling complex that plays an important role in the survival of malignant B cells. IMBRUVICA blocks signals that tell malignant B cells to grow and divide uncontrollably. IMBRUVICA has been granted three Breakthrough Therapy Designations by the FDA, a first for an oncology drug. These designations are intended to expedite the development and review of drugs for serious or life-threatening conditions.

"It is important that we work with a development partner with expertise in both clinical and commercial supply, as well as U.S. and worldwide GMP regulations, to ensure reliable quality supply to patients," commented Heow Tan, Chief of Technical Operations at Pharmacyclics. "STA's extensive experience will help us meet the demands of clinical and commercial supply for IMBRUVICA."

"We are very pleased and honored that Pharmacyclics has selected STA, WuXi's small-molecule development and manufacturing business unit, as a key partner for this supply," said Dr. Ge Li, Chairman and CEO of WuXi. "WuXi is determined to help our partners introduce innovative breakthrough drugs like IMBRUVICA to benefit patients around the world."