BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

CASI, Yiling Wanzhou team up to manufacture entecavir, cilostazol

June 25, 2018 | News

The contracted manufacturing facilities have been inspected by both the U.S. Food and Drug Administration (FDA) and China FDA (CFDA).



CASI Pharmaceuticals, Inc., a biopharmaceutical company dedicated to the development and delivery of high quality, cost-effective pharmaceutical products and innovative therapeutics to patients in the U.S., China and throughout the world, has announced a strategic and long-term manufacturing agreement with Yiling Wanzhou International Pharmaceutical Co., Ltd. for the manufacturing of entecavir and cilostazol.

Yiling Wanzhou International Pharmaceutical Co., Ltd. is a subsidiary of Shijiazhuang Yiling Pharmaceutical Co. Ltd. The contracted manufacturing facilities have been inspected by both the U.S. Food and Drug Administration (FDA) and China FDA (CFDA) and operate to strict International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Manufacturing Practice (GMP) standards, which will enable CASI to eventually sell both entecavir and cilostazol in the U.S., China and worldwide markets. Entecavir and cilostazol are part of the 29 abbreviated new drug applications (ANDAs) that CASI acquired from Sandoz in January 2018.

The FDA approved entecavir in 2005 for the treatment of chronic hepatitis B viral (HBV) infection. Entecavir is an HBV nucleoside analog reverse transcription inhibitor that interferes with HBV replication. The 2016 estimated sales in China for entecavir were approximately $1.5 billion.

The FDA approved cilostazol in 2006 for the reduction of symptoms of intermittent claudication.2 Cilostazol is a PDE-III inhibitor. Cilostazol inhibits platelet aggregation, improves endothelial cell function, and acts as a vasodilator enabling blood to move more easily through peripheral blood vessels. The 2016 estimated sales in China for cilostazol were approximately $65 million.