

Kitov Pharma inks deal with China's Changshan Pharma

15 May 2018 | News

The deal grants exclusive rights to import, manufacture and distribute its lead drug candidate, Consensi, in China



Israel-based Kitov Pharma, an innovative biopharmaceutical company, has signed a definitive license and commercialization agreement for the Chinese market, granting exclusive rights to import, manufacture and distribute its lead drug candidate, Consensi, in China to Hebei Changshan Biochemical Pharmaceutical.

Consensi, formerly known as KIT-302, is a combination drug intended to simultaneously treat pain caused by osteoarthritis, and hypertension, which is a common side effect of stand-alone drugs that treat osteoarthritis pain. Consensi is comprised of two FDA-approved drugs, celecoxib (Celebrex®), a non-steroidal anti-inflammatory COX-2 inhibitor (NSAID) for the treatment of pain caused by osteoarthritis, and amlodipine besylate (Norvasc®), a calcium channel blocker for lowering blood pressure.

Upon receipt of marketing authorization in China, Changshan Pharma will have the exclusive right and license to import, manufacture, distribute, and sell Consensi™ in China, Taiwan, Hong Kong, and Macao. Changshan Pharma will be responsible for financing and seeking regulatory approval for Consensi™ in China. Under the terms of the agreement, Kitov is entitled to receive up to an aggregate of \$3.5 million for U.S. FDA approval of Consensi™, which has a PDUFA date of May 31, 2018, and for China regulatory milestones; up to an aggregate of \$6.0 million for predefined commercial milestones; and up to 12% royalties on net sales.

"We are extremely pleased to enter into this commercialization agreement for Consensi™ and look forward to building a long-term relationship with Changshan Pharma in China. Changshan Pharma has a strong track record of successfully launching and marketing pharmaceutical products in China," said Dr. Gil Ben-Menachem, Kitov's Vice President - Business Development. "This is the second commercialization agreement for Consensi™ in Asia, further confirming its global sales potential. Kitov continues to work diligently towards finalizing additional commercialization agreements in the U.S. and in other territories."

"We believe that Consensi™ has substantial commercial potential in China and will provide significant benefit to Chinese patients. We are well-positioned to maximize the value of this product in the Chinese market, and look forward to seeking

regulatory approval and launching Consensi™ in China,” said Mr. Shuhua Gao, Chairman and General Manager of Changshan Pharma.

The total annual NSAID market in China is estimated at hundreds of millions of dollars, according to IMS. Moreover, celecoxib sales in China represented 25% of the total NSAID market. In recent years, sales of selective COX-2 inhibitors (coxibs), and especially Celebrex® (Pfizer’s branded celecoxib), have been increasing in China at an annual rate of 25 percent.