



CHINA'S LIFE SCIENCE INDUSTRY 11-12/15

Dear Friends and Colleagues,

In December, the CFDA realized the long discussed reforms designed to accelerate the regulatory review of new drugs.

These policy changes expand the categories for new drug applications which are eligible for a "fast track" and introduce improved and streamlined regulatory requirements to remove bureaucratic hurdles from the drug development procedure.

Having the second biggest health market in the world and burdened by an aging population, China's policy reforms are yet another step in bringing the Chinese people much closer to better and more affordable remedies.

We'd like to wish you and your loved-ones a happy and healthy 2016 as well as to advance our warmest wishes for the New Year of the Monkey. 恭喜发财!

Eyal Harel

CEO-Global

NEWS FROM THE INDUSTRY

Sihuan and RaQualia to Collaborate on Analgesic Drugs

On December 22, 2015 the Sihuan Pharmaceutical Holdings Group Ltd. announced that its subsidiary, Shandong XuanZhu Pharma, and Japanese RaQualia Pharma Inc. entered into a research collaboration agreement. The collaboration will focus on developing pre-clinical compounds for a specific ion channel target. Pursuant to the terms of

the Agreement, RaQualia and the Group will work collaboratively to identify valuable drug candidates during the three-year collaboration period. The parties also agree to jointly promote the global market development for such candidates. The Group will be granted with exclusive rights to develop, manufacture and market the drug candidates in the Greater China Region and will share the income generated from markets outside of the Greater China Region.

Kehua Acquires Italian Technogenetics and Joint Ventures with Altergon on IVD Assets

Dec. 21, 2015: KHB Shanghai Kehua Bio-Engineering Co. announced the closure of a deal with Italian Technogenetics finalizing the acquisition of Technogenetics' IVD Assets.

Under the terms of the agreement KHB has acquired 100% of Technogenetics with an investment of 28.8 million Euro, 18.8 million Euro used for the acquisition and the rest for the business development of the joint venture in the following 18 months.

Once the acquisition is finalized, KHB will form a joint venture with Altergon Italia, which will contribute its IVD's spin-off to the joint venture, including its R&D premises in South Italy and China. KHB will hold 80% and Altergon the remaining 20% of the share capital of the joint venture.

SciClone to Pursue Development of SGX942 in China Following Report of Positive Phase 2 Preliminary Results in Oral Mucositis

SciClone Pharmaceuticals, Inc. announced on Dec. 21, 2015 that it plans to pursue development and registration of SGX942 in the Greater China market, for the treatment of oral mucositis. SGX942 is being developed by Soligenix, Inc., which recently reported positive preliminary results from its Phase 2 clinical trial for the treatment of oral mucositis in head and neck cancer. SGX942 is an innate defense regulator (IDR), a new class of

short, synthetic peptides, with a novel mechanism of action in that it modulates the body's reaction to both injury and infection towards an anti-inflammatory and an anti-infective response. The Phase 2 preliminary results reported by Soligenix showed a significant reduction in the duration of severe oral mucositis in patients receiving chemoradiation therapy for treatment of their head and neck cancer.

Uni-Bio Science Acquires Global Rights to Type 2 Diabetes Drug Mitiglinide from Jiangsu Hansoh Pharmaceutical Co. Ltd

November 24, 2015: Uni-Bio Science Group Limited announced that it will acquire the exclusive global rights to manufacture and commercialise mitiglinide, a new oral antidiabetic agent, from Jiangsu Hansoh Pharmaceutical Co. Ltd.

Mitiglinide is a new, oral antidiabetic agent which belongs to the glinides class of blood glucose lowering compounds. It is known to improve postprandial hyperglycemia in patients with Type 2 diabetes and has received new drug approval as a first and/or second line of treatment for the disease from the China Food and Drug Administration. It is the market leader of the glinides class of Type 2 diabetes treatments in Japan, generating \$140 million in revenue in 2014.

Hansoh has developed its own version of mitiglinide, which is currently being marketed and sold in China.

Under the terms of the agreement, Uni-Bio will manufacture the drug in its CGMP-certified plant in Beijing and market it in China. In other markets Uni-Bio will seek distribution partners.

Lee's Pharma Licenses Solasia's Anti-Nausea Patch in China

Japanese Solasia Pharma K.K. and Lee's Pharmaceutical Holdings Limited announced on November 25, 2015 that they have entered into an exclusive license agreement for the commercialization and promotion of Sancuso® (granisetron transdermal delivery system) in China, excluding three major cities (Beijing, Shanghai and Guangzhou).

Under the terms of the agreement, the license includes the right to commercialize Sancuso® for the patients suffering from chemotherapy-induced nausea and vomiting (CINV).

Solasia obtained an exclusive license to develop and commercialize Sancuso® for Asian territories from ProStrakan and is currently waiting for approval from the China Food and Drug Administration.

ZAI Lab and Hanmi Execute a License Agreement to Develop Novel EGFR Targeted Therapy for Lung Cancer in China

ZAI Lab Limited and Hanmi Pharm. Co., Ltd. announced on November 23, 2015 that they have executed a collaboration and license agreement under which ZAI Lab will acquire exclusive rights in China, Hong Kong and Macau to develop,

manufacture and commercialize HM61713, a novel, third-generation EGFR targeted therapy for the treatment of EGFR mutation positive lung cancer.

The total amount agreed to be paid by ZAI Lab was \$92 million as well as 10% royalties from sales.