CHINA'S LIFE SCIENCE INDUSTRY 10-12/17

Dear Friends and Colleagues,

After a few months of deliberations, a new directive was finally issued by China's State Council: The directive is designed to accelerate China's regulatory approval process for drugs and medical devices, allowing foreign trial data to be used for local approvals. This is yet another step taken by the Chinese authorities to bring the CFDA regulations in line with those of regulators in most developed countries and is expected to reduce costs and time to market for these much-needed remedies locally.

I'd like to take the opportunity and wish you and your loved ones a Merry Christmas, a healthy and prosperous New Year of 2018 and a New Chinese Year of the Dog! **恭喜发财!**

Eyal Harel
CEO-Global

NEWS FROM THE INDUSTRY

Shenzhen BioScien Licenses the China Rights of a Prostate Cancer Vaccine from Generex

December 7, 2017. Generex Biotechnology announced that its wholly-owned subsidiary, Antigen Express, has entered into a License and Research Agreement with Shenzhen BioScien Pharmaceuticals Co. Ltd. to develop and commercialize the Antigen Express AE37 immunotherapeutic vaccine for prostate cancer in China (including Taiwan, Hong Kong, and Macau).

A previously completed Phase I study of the vaccine conducted by Antigen Express in patients with prostate cancer demonstrated robust, long-term, and specific activation of cancer-fighting T cells in immunized patients.

Shenzhen BioScien will pay Generex a non-refundable, up-front license fee of

$700,000 USD. Under the Agreement, Shenzhen BioScien will also make milestone payments to Generex of $1 million each upon completion of the Phase II and Phase III clinical studies of the vaccine as well as a milestone payment of $2 million upon regulatory approval of the vaccine in China. In addition, Generex will receive 10% royalty payments on net sales of the product in China.

Arena Pharmaceuticals and Everest Medicines enter into a Partnership for Drug Development in China

December 5, 2017. Arena Pharmaceuticals and Everest Medicines have entered into a development and commercialization partnership for ralinepag and etrasimod in mainland China, Taiwan, Hong Kong, Macau, and South Korea. In this context, C-Bridge Capital has invested $50 million to fund Everest and has assembled a veteran leadership team with an established track record in the development of innovative drugs and commercialization in China and globally. The companies aim to rapidly advance the product towards approval and launch.

LivaNova Enters into an LOI to Sell its Cardiac Rhythm Management Business Franchise to MicroPort for $190 Million

Nov. 20, 2017. LivaNova and MicroPort have entered into a binding LOI for the sale of LivaNova's Cardiac Rhythm Management ("CRM") Business Franchise to MicroPort for $190 million.

The CRM Business Franchise develops, manufactures and markets products for the diagnosis, treatment and management of heart rhythm disorders and heart failures. CRM products include high-voltage defibrillators, cardiac resynchronization therapy devices and low-voltage pacemakers. The CRM Business Franchise generated approximately $249 million in net sales in the fiscal year 2016 and has approximately 900 employees with operations chiefly in Clamart, France; Saluggia, Italy; and Santo Domingo, Dominican Republic.

Oncolytics Biotech and Adlai Nortye Enter into US$86.6 Million Regional Licensing Agreement

November 16, 2017. Oncolytics Biotech, a biotech company developing REOLYSIN®, an intravenously delivered immuno-oncolytic virus that activates the innate and adaptive immune systems to turn 'cold' tumors 'hot', announced that it has entered into a regional licensing agreement with China-based Adlai Nortye, a biopharmaceutical company. Under the terms of the agreement, Adlai will have exclusive development and commercialization rights to REOLYSIN® in China, Hong Kong, Macau, Singapore, South Korea and Taiwan.

Oncolytics is to receive upfront, licensing and milestone payments to support a phase 3 registration study of USD $21.2 million, and will be eligible to receive up to U$65.4 million upon achieving clinical, regulatory and commercialization milestones as well as double-digit royalty

payments.

Huahai In-licenses Immuno-Oncology Drug in a $65 Million Deal

Nov. 6, 2017. Eutilex Co. Ltd. has entered into a strategic partnership with China's fast-growing Zhejiang Huahai Pharmaceutical Ltd.

According to the agreement, Huahai takes a $30 million equity stake in Eutilex and receives an exclusive license to develop and commercialize EU-101, a humanized monoclonal antibody developed by Eutilex for cancer treatment, in the People's Republic of China, Taiwan, Hong Kong and Macau.

In early preclinical studies, EU-101 has demonstrated efficacy against tumors by activating essential parts of the immune system.

Eutilex will be eligible for milestone payments up to $35 million for 10 approved immuno-oncology indications, as well as for royalties from future Huahai sales.

Huahai will be eligible to participate in Eutilex's worldwide licensing revenues and will receive royalties from Eutilex's EU-101 global sales.

Xynomic In-Licenses RAF Inhibitor from Boehringer in a $502 Million Deal

Oct. 30, 2017. Xynomic Pharma has acquired exclusive global rights to develop, manufacture and commercialize BI 882370, a 2nd-generation RAF inhibitor, from Boehringer Ingelheim. Under the terms of the agreement Xynomic will pay upfront, milestone and royalty payments up to $502 million.

BI 882370 is a potent and selective RAF inhibitor uniquely binding to the DFG-out conformation, whereas marketed BRAF inhibitors occupy the DFG-in conformation. BI 882370 inhibited proliferation of BRAFmut melanoma cell lines with 100x higher potency (EC50 1 – 10 nM) than vemurafenib (VEM), a marketed BRAF inhibitor.