CHINA'S LIFE SCIENCE INDUSTRY 4-6/17

Dear Friends and Colleagues,

On June 19, 2017, the CFDA was accepted as a full member in the ICH – the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use. The Council serves as a regulatory forum designed to enable the harmonization, where possible, of technical standards for drug registration. The CFDA's acceptance by the ICH is a confirmation of the progress it has made towards introducing international standards to China's drug approval system. We have covered many of these reforms in the recent past, while many more have been recently introduced, as detailed in this newsletter.

On a personal note, we would like to congratulate oncgnostics and CJMT, a Sinopharm subsidiary, for successfully closing distribution and licensing agreements, in which we took an active role.

Last, we'd like to take the opportunity and wish you and your loved ones a comfortable summer vacation and safe travels!

Eyal Harel

CEO-Global

POLICY NEWS

CFDA Clears the Path for Early Integration of Global Clinical Trials in China

The CFDA has issued draft guidelines in mid-March that would allow foreign pharma companies to run Phase I trials in China in the context of their global development, for the first time. This draft also proposes the removal of the existing requirement for local drug applications to be locally manufactured.

Further Reforms in Approval Process for Clinical Trials

As announced on May 11, 2017, China's CFDA is backing away from its certification system, currently requiring any applicant for clinical trials to go through a laborious certification process (usually taking 12-18 months), and switch to the "US style" - "no response means approval" mechanism.

Under the new scheme, rather than waiting for a "green light" from the CFDA

prior to starting a clinical trial, an applicant will have an automatic approval if the agency hasn't rejected the applications within 60 working days.

NEWS FROM THE INDUSTRY

oncgnostics Grants Exclusive License for GynTect to Sinopharm Subsidiary

April 5, 2017: The Chinese pharma company Changchun Jienuo Medical Technology (CJMT), a subsidiary of the Chinese state-owned Sinopharm Group, has obtained an exclusive license from the German company oncgnostics for marketing GynTect® in China, Hongkong and Macao. Under the contract, oncgnostics will be entitled to undisclosed upfront, milestone and royalty payments.

BeiGene Presents Positive Phase 1 Results from its BTK Inhibitor

On June 16, 2017 BeiGene Ltd., a clinical-stage biopharmaceutical company developing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, presented its initial clinical data from an ongoing Phase I trial of the Bruton's Tyrosine Kinase (BTK) inhibitor BGB-3111 combined with the anti-CD20 antibody obinutuzumab in patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) and follicular lymphoma (FL). The initial Phase 1 data demonstrates that the combination is well tolerated with an overall response rate (ORR) of 89% including complete responses (CRs) in 22% of treatment naïve (TN) CLL/SLL patients, an ORR of 92% with CRs in 16% of relapsed/refractory (R/R) CLL/SLL patients, and an ORR of 73% with CRs in 33% of R/R FL patients.

Kanghong Signs an MOU for a full purchase of IOPtima

On April 19, 2017 Chengdu Kanghong Pharma and Israel-based IOPtima Ltd. signed a non-binding memorandum of understanding for a full purchase in stages of IOPtima.

In the first stage, Kanghong will invest $7 million in IOPtima against 19% of its share capital. In the second stage, Kanghong may acquire additional shares from IOPtima's shareholders for an additional $17.2 million, at a company value of $ 42 million, thus increase its holding to 60%. In the third and fourth stages - Kanghong may acquire the remaining 40% of the holdings at a company valuation that will reflect the IOPtima's business at the time of acquisition.

Alamab Purchases Rights for two Experimental Drugs paying $4.5 million upfront

AlaMab Therapeutics, a subsidiary of the China-based CSPC Pharmaceutical Group is licensing two experimental drugs from two University of Texas research institutions for an initial $4.5 million upfront payment. The Texas institutions could receive more money if the drugs meet clinical and regulatory goals.

One of the preclinical compounds being licensed aims to suppress damage after a spinal cord injury while the other is targeting breast cancer metastasis to the

bone.

In addition to the upfront payment, AlaMab may pay additional $114 million in royalty payments and subject to meeting certain commercial milestones.

China Meheco Acquires Control in Hainan General for ~$42 million

June 7, 2017. China Meheco, ranked among the top 10 import & export enterprises in the pharmaceutical industry, is acquiring 54% of Hainan General Sanyang Pharmaceutical Co., Ltd. a manufacturer and producer of a antibiotic-resistant high-enzyme complex.

Lombard Medical and MicroPort Scientific Corporation Finalize Strategic Partnership Agreement

On April 3, 2017, Lombard Medical, Inc., a medical device company focused on endovascular aneurysm repair, and MicroPort Scientific Corporation, a leading global manufacturer and marketer of a diversified portfolio of medical devices, announced their agreement to form a strategic partnership.

The partnership will allow Lombard to accelerate commercialization in China and other global markets for its abdominal aortic aneurysms (AAA) product portfolio.

MicroPort will manufacture, in its facilities in Shanghai, certain components for the Lombard's Aorfix and Altura product lines. It is anticipated that MicroPort will begin providing components to Lombard in the second half of 2017.

MicroPort has the exclusive marketing rights for the Lombard product portfolio for China and Brazil as well as a technology license to manufacture the products for the Chinese market. MicroPort expects to launch Aorfix in China after gaining CFDA approval which is anticipated in the second half of 2018.