CHINA'S LIFE SCIENCE INDUSTRY 1-3/17

Dear Friends and Colleagues,

After 8 years of stagnation, China has finally expanded its list of medicines covered nationwide by government insurance, increasing it by ~15% to 2,535 drugs. Some 50% of the drugs on the list are Western drugs, and the rest are Chinese.

This move was complemented by the CFDA's announcement of its intent to remove various obstacles from the registration path of foreign approved drugs (more on that in our policy news section).

These changes underline China's distinct and ongoing efforts to deliver better and more affordable healthcare to its citizens. These are also good news for the pharmaceutical industry, which will benefit from easier and faster access to China's health market as well as its patient-pool for clinical trials.

We'd like to take the opportunity and wish you and your loved ones a happy Passover and happy Easter holidays.

Eyal Harel

CEO-Global

POLICY NEWS

CFDA Proposes Changes to Foreign Drug Registration

March 17, 2017. The CFDA has published suggested amendments to its foreign drug registration rules. The proposed amendments are designed to overcome the present hurdles associated with foreign-approved drug registration in China.

The proposal suggests opening up China to multi-center global trials and admitting the results obtained from such trials in the local drug registration process.

If implemented, the proposal may save years of local parallel development and shorten the time-to-market of new drugs, to the benefit of both pharma companies and the general public.

NEWS FROM THE INDUSTRY

Kite and Fosun Establish JV in China to Develop and Commercialize Autologous T-Cell Therapies to Treat Cancer

On January 10. 2017 KitePharma and Shanghai Fosun Pharmaceutical (Group) announced the formation of a joint venture to develop, manufacture and commercialize Kite's axicabtagene ciloleucel in China with the option to include additional products, including two T cell receptor (TCR) product candidates from Kite.

The joint venture will be registered in Shanghai and owned equally by Kite Pharma and Fosun Pharma.

Under the terms of the agreement, Fosun Pharma will provide $20 million in funding to support clinical development and manufacturing activities while Kite will provide certain technical transfer services. Each party will share in any profits from the joint venture, with Kite Pharma receiving 40 percent and Fosun Pharma receiving 60 percent. Kite will also receive an upfront fee of $40 million , as well as regulatory and commercial milestones totaling $35 million and sales royalties for axicabtagene ciloleucel.

Valeant to Sell Dendreon to the Sanpower Group For $819.9 Million

Jan. 9, 2017. Valeant Pharmaceuticals International, Inc. has announced that its affiliate entered into a definitive agreement to sell all of the outstanding equity interests in Dendreon Pharmaceuticals, Inc. to the Sanpower Group Co. Ltd., one of the largest privately owned conglomerates in China. Under the terms of the transaction, Valeant will receive a cash consideration of $819.9 million at completion.

Dendreon's first and only commercialized product is Provenge®, an autologous cellular immunotherapy (vaccine) for prostate cancer treatment approved by the FDA in April 2010.

Neovacs and Biosense Sign Option Agreement for Chinese Development and Commercialization for Lupus and Dermatomyositis Treatment

February 21, 2017. Neovacs and BioSense Global LLC have signed a commercial license option agreement for the IFNα Kinoid vaccine to treat lupus and dermatomyositis in China. The agreement is worth up to €65 million in upfront and milestone payments, not including double-digit sales royalties.

Chi-Med Announces Positive Results in its Phase III Pivotal Registration Trial for a Metastatic Colorectal Cancer Drug

On March 3, 2017 Hutchison China MediTech Limited ("Chi-Med") reported that it had finished its Phase III pivotal registration trial for fruquintinib with top line results. The drug was tested in 416 Chinese patients with locally advanced or metastatic colorectal cancer ("CRC") who failed at least two prior chemotherapies, including fluoropyrimidine, oxaliplatin and irinotecan.

The trial met its primary endpoint of demonstrating a clinically meaningful and a statistically significant increase in

overall survival ("OS") in patients treated with fruquintinib as compared to patients treated with a placebo. Chi-Med is currently preparing to submit a new drug application for fruquintinib to the China Food and Drug Administration.

In addition to OS, a statistically significant improvement in progression-free survival, a key secondary endpoint, was observed. The adverse events demonstrated in the trial did not identify any new or unexpected safety issues.

BeiGene and Guangzhou Development District Establish Joint Venture to Build Biologics Manufacturing Facility

BeiGene Ltd., the Guangzhou Development District and Guangzhou GET Technology Development Co., Ltd have entered into a definitive agreement to establish a state-of-the-art commercial-scale biologics manufacturing facility in Guangzhou, Guangdong Province. The joint venture, BeiGene Biologics Co., Ltd. will also provide funding for research and development of biologic drug candidates in China. Total direct investments are expected to amount to $330 million.