CHINA'S LIFE SCIENCE INDUSTRY 01-02/13

Dear Friends and Colleagues,

For many years, new drugs and devices to be approved by China's SFDA had to pass high bureaucratic barriers in the form of very long waiting lists. This meant that local patients had to endure long periods before existing treatments became available in China.

A recent policy change announced by the SFDA is going to change all that: In a regulatory reform the SFDA is planning to give preferential treatment to innovative drugs and devices, in particular where such new technology provides treatment for unmet needs, and is expected to drastically shorten registration time for innovative technologies, while providing a strong disincentive for "me-too" generics in fields where supply exceeds demand.

This reform goes hand in hand with other policies designed to provide the general population with higher accessibility to medical treatment (for another example see price-cuts below), as laid out in the 11th and 12th five-year-plan.

We wish you a Happy and Kosher Pessach!

Eyal Harel
Co-CEO

POLICY NEWS

China's SFDA Wants to Cut Number of Drug Distribution Companies by 10,000

Feb. 20, 2013. China's SFDA has announced a set of newly-revised regulations for the country's drug distributors. These new Good Supply Practices (GSP) for drugs will promote higher standards of protection which should reduce the number of China's drug wholesalers from a current 13,000 to just 3,000, a draconian rollup of the country's highly fragmented distribution system.

China Cuts Medication Prices

January 8, 2013. In a fourth price-cut since 2011, China has ordered price

reductions which average between 15-20% for drugs in twenty broad classes of medicines. As this attempt to make medicine more affordable to the general population is designed to hit high-end, expensive drugs the hardest, its deepest impact will be on the business of multinationals in China.

NEWS FROM THE INDUSTRY

Sihuan Granted SFDA Approval to Test New Drugs

February 22, 2013. Sihuan Pharma announced that it had received permission from the SFDA to begin clinical trials of two of its drug-candidates: Pinoxacin Hydrochloride, a Category 1.1 drug for the treatment of Type II Diabetes; and Benapenem, also a Category 1.1 drug, for the treatment of multiple drug resistance ("MDR"). The Beijing-based company said it would start a Phase I trial in both drug-candidates in the first half of 2013.

Lee's Pharma Subsidiary In-Licenses Dyax Drug for China-use

February 7, 2013. Dyax Corp., a developer of novel biotherapeutics and CVie Therapeutics, a subsidiary of Lee's Pharmaceutical, announced a strategic partnership for the development and commercialization of KALBITOR® in the treatment of hereditary angioedema (HAE) and other angioedema indications in China, Hong Kong and Macau.

KALBITOR is currently marketed in the United States for the treatment of acute attacks of HAE in patients 16 years of age and older.

Under the terms of the exclusive license agreement, Dyax will receive an upfront payment and is eligible to receive future development, regulatory and sales milestones. Dyax is also eligible to receive royalty on net product sales. CVie is solely responsible for all costs associated with development, regulatory activities, and the commercialization of KALBITOR in China, Hong Kong and Macau. Additionally, CVie will purchase drug products from Dyax on a cost-plus basis for commercial supply.

China's Grandhope Biotech In-licenses Stem Cell Technology from Orthocell

February 4, 2013. Guangzhou-based Grandhope Biotech has in-licensed the China rights to an autologous stem cell tendon-repair technology from the Australian firm Orthocell Limited. The technology harvests healthy tendon cells from the patient, cultures them, and then implants a mixture of the cells and a scaffolding matrix to the damaged tendon. Terms of the agreement were not disclosed.

Lee's Pharma Gains Negotiation Option for China Rights to Anticoagulant

January 29, 2013. Portola Pharmaceuticals and Lee's Pharmaceutical have announced an agreement to jointly expand the Phase 3 APEX study of betrixaban, with an option to negotiate the commercial rights to the drug in China. The APEX Study is evaluating betrixaban, a novel oral, once-daily Factor Xa inhibitor for extended duration venous

thromboembolism (VTE) prophylaxis, for superiority compared with the current standard of care in acutely ill patients. If successful, betrixaban will be the first novel oral anticoagulant approved for use in this indication and the first anticoagulant approved for extended duration VTE prophylaxis in the acutely ill patient population.

Under the agreement, Lee's will provide Portola with upfront and continuing payments to support the expansion of the APEX study into China and work with Portola to identy leading clinicians and clinical sites to participate in the study. Lee's will also lead regulatory interactions with China's SFDA. Following completion of the study, Lee's will have an exclusive period in which to negotiate the commercial rights to betrixaban in China.

Stryker Buys Trauson, a Chinese Orthopedic Company, for $764 Million

January 17, 2013. Stryker and Trauson have announced Stryker's offer to acquire all the shares of Trauson for HK$7.50 per ordinary share for a total consideration of $764 million in an all cash transaction.

The acquisition was completed on March 1,, 2013.

Zhifei Biological Approved to Begin Phase III Trial of TB Vaccine

Chongqing Zhifei Biological announced on January 11, 2013 that it was granted SFDA approval to begin a Phase III trial for its Mycobacterium Vaccae for injection (Vaccae). The product will be tested in clinical trials for the prevention of tuberculosis.