



CHINA'S LIFE SCIENCE INDUSTRY 09-10/12

Dear Friends and Colleagues,

As China's healthcare market is becoming more competitive, foreign drug and medical device makers are seeking alternative business models in China. GE Healthcare, for example, is developing primary care products suitable for use in local clinics, which make up one of the fastest growing segments in China's health market. Medtronic, using a different approach, purchased Kanghui Holdings, a Chinese device company, for \$816 million, a deal designed to use Kanghui's well-established sales connections in smaller cities and rural areas.

We would like to take the opportunity to wish you all a Happy Hannuka and Merry Christmas!

Yours Sincerely,


Eyal Harel

CEO

POLICY

SFDA Releases 2011 Drug and Clinical Trial Approval Report

October 9, 2012. In 2011, the SFDA issued fewer drug approvals and allowed a smaller number of clinical trials than in 2010. On the other hand, the agency received a larger number of applications for drug registration. In total, the SFDA approved 718 drug registrations last year, a reduction of 29% compared to the

previous year. In addition, the agency approved 621 applications to begin clinical trials, a decline of 32% compared to 2010. However, 3,620 applications for drug registrations meant an increase of 18% since 2010.

China Announces another Round of Drug Price Cuts

China has ordered an average 17% reduction in the maximum retail prices of 95 different cancer, immunology and

blood-related drugs, many of which are produced by foreign drug makers. Unlike earlier rounds of price cuts, this one concentrated on drugs with high daily costs. Especially hard hit were drugs with “separated pricing” – the drugs available from a foreign manufacturer at a higher price than their China generic equivalents. At the same time, China’s NDRC reiterated support for prices that are high enough to encourage innovative drug research.

INDUSTRY

AstraZeneca Signs \$150 Million Deal with Ironwood Pharma

October 23, 2012. AstraZeneca and Ironwood Pharma have announced an agreement to co-develop and co-commercialise Ironwood’s linaclotide in China. Linaclotide is the first and only guanylate cyclase-C (GC-C) agonist approved by the US FDA, in August, for irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC).

In May, Ironwood filed a clinical trial application with the SFDA in China for a Phase III clinical trial to assess the efficacy and safety of linaclotide in adult patients suffering from irritable bowel syndrome with constipation (IBS-C).

AstraZeneca and Ironwood are jointly responsible for strategic oversight of the development and commercialization of linaclotide in China. AstraZeneca will

have primary responsibility for the local operational execution.

Under the terms of the collaboration, AstraZeneca will make an upfront payment of \$25 million to Ironwood and will share the net profits and losses associated with linaclotide in China. Ironwood will also be eligible for \$125 million in additional commercial milestone payments contingent on the achievement of certain sales targets.

WuXi AppTec Opens China’s First GMP Biologics Facility

October 16, 2012. WuXi AppTech has officially opened its GMP manufacturing facility for biologic drugs – the first such facility in China which is compliant with GMP standards of China, the US and Europe. WuXi has constructed a facility that is state-of-the-art, including the first operation anywhere in the world that uses 100% disposable equipment for producing biological drug substances.

RuiYi In-Licenses Cancer/ Anti-Inflammatory mAb

October 5, 2012. RuiYi, a drug discovery company based in San Diego and Shanghai, has obtained world-wide rights to an IL-6 mAb from ArGEN-X, a Dutch company. The molecule is being developed as a potential treatment for cancer and inflammatory diseases.