CHINA'S LIFE SCIENCE INDUSTRY 06-08/15

Dear Friends and Colleagues,

CFDA regulations are undergoing tectonic changes with new reforms expected to ease and expedite the registration and introduction of new therapies for the Chinese market.

These changes include dramatically shortening the time required for local IND reviews, easing regulations governing China-global clinical trials of novel drugs as well as allowing more data from global trials to be considered in the local registration process of innovative products.

These positive developments will allow China to play a bigger role in the global health care market not only as a future market but also as an attractive place-of-choice for the development of pharmaceuticals.

With this good news we would like to wish you a happy Jewish New Year and a Merry Mid-Autumn Festival.

Shanah Tovah and 中秋快乐!

Eyal Harel

CEO-Global

POLICY RELATED NEWS

Shortened IND Approvals for Oncology Drugs

The CFDA is expected to expedite IND approvals for drugs.

Under the current situation, companies have to wait 18-24 months before they are allowed to commence clinical trials on new drugs. According to the new regulations decisions will have to be made within 60 days.

The pilot program will be implemented initially on oncology drugs only and will be expanded to include additional indications subject to its successful implementation.

NEWS FROM THE INDUSTRY

BioQuiddity and Lee's Pharmaceutical to Jointly Commercialize Two Infusion Drugs

On August 24, 2015 BioQuiddity Incorporated and Lee's Pharmaceutical (HK) Limited announced the signing of a strategic license and supply agreement for the registration and commercialization of BioQuiddity's ropivacaine and propofol infusion pharmaceutical products in the PRC, Taiwan, Hong Kong, and Macau.

BioQuiddity's unit-dose infusible pharmaceuticals are comprised of the pharmaceutical, delivery system and administration line in a self-contained, single use, ready-to-use presentation. The ropivacaine pharmaceutical is prefilled with 0.2% ropivacaine and is intended to provide a safer, more efficient continuous-infusion post-operative pain solution. BioQuiddity's propofol infusion pharmaceutical features both programmable flow and bolus capabilities.

BeiGene Commences Phase Ib Study of its Novel 2nd Generation B-RAF inhibitor

BeiGene, Ltd., an innovative oncology company focused on developing targeted and immune-oncology therapeutics, announced on July 13, 20105 that it has treated its first patient in a Phase Ib clinical trial for BGB-283, a second generation B-RAF inhibitor.

This study is designed to determine the efficacy of a daily oral dosing regimen for BGB-283 in solid tumors that harbor BRAF mutations and/or aberrations in the RAS-MAPK (mitogen-activated protein kinase) pathway. The study is being conducted across multiple centers in Australia and New Zealand.

The Phase Ib study being undertaken by BeiGene follows the successful completion of a Phase Ia dose escalation study in patients who have B-RAF or K-RAS mutations. In this study, BGB-283 demonstrated a good safety profile along with promising early clinical activity in patients harboring mutations that previously could not be targeted by first generation B-RAF inhibitors.

Resverlogix Closes License Agreement and Enters Into Definitive Stock Purchase Agreement with Hepalink

On Jul 8, 2015 Resverlogix Corp. announced that it had closed a license agreement with Shenzhen Hepalink Pharmaceutical Co., Ltd.

Under the license agreement, Resverlogix will be eligible to receive sales-based milestone payments from Hepalink, each ranging fromUS$5 million to US$90 million, provided its RVX-208 will reach certain annual sales milestones in China, Hong Kong

and Macau. In addition, Hepalink will pay Resverlogix a royalty in the amount of 6% of net sales for the drug in these territories, subject to certain adjustments.

It was agreed that Hepalink will be responsible for all clinical and development costs, including a patient population that will be included in Resverlogix's planned Phase 3 BETonMACE trial.

The companies also announced the closing of a $50 million dollar private placement investment in Resverlogix, made by Hepalink and Eastern Capital.

Apogenix Enters into Licensing Agreement with CANbridge Life Sciences for Immuno-Oncology Candidate in China

Apogenix, a next generation immuno-oncology company, announced on July 15, 2015 that it had entered into an exclusive licensing agreement with CANbridge Life Sciences, a biopharmaceutical company focused on developing Western drug candidates in China and North Asia. The agreement allows for the development and commercialization of lead immuno-oncology drug candidate APG101 in China, Macao, and Hong Kong. Under the terms of the agreement, Apogenix will receive upfront and milestone payments, as well as royalty payments at tiered, double-digit royalty rates following commercial launch of APG101 in China. APG101 is a CD95 ligand inhibitor which restores the immune response against tumors and inhibits invasive tumor cell growth. The drug candidate is being developed for the treatment of solid tumors and malignant hematological diseases. In a controlled phase II proof-of-concept trial in patients with recurrent glioblastoma, treatment with APG101 in combination with radiotherapy has demonstrated clinical superiority in all study endpoints compared to treatment with radiotherapy alone.

Israel's HBL Receives $2 Million from Chinese Investors

June 28, 2015: Hadasit Bio Holdings, a holding company for medical technology developed at Hadassah Medical Center in Jerusalem, announced a $2 million investment from unspecified Chinese investors. The investors will receive 25% of the company's shares and preferential treatment on China rights to any of HBL's products.

3SBio Acquires Global Rights to Apexigen's Anti-TNF mAb

3SBio Inc., a leading China-based biotechnology company focused on researching, developing, manufacturing and marketing biopharmaceutical products announced on June 22, 2015 that it has acquired the ex-China global rights to Apexigen's anti-TNF

monoclonal antibody ("mAb") technology.

3SBio previously acquired the China rights from Apexigen in 2006. 3SBio's anti-TNF mAb, designated SSS07, has completed pre-clinical testing and demonstrated higher potency than the best-known available TNF inhibitors, including adalimumab and infliximab, potentially improving treatment options for patients with rheumatoid arthritis and other inflammatory diseases.

In March 2015, 3SBio initiated a dose-escalating Phase I trial for SSS07 in China (NCT02460393). A Phase 1b trial is also scheduled to start in early 2016 using multiple doses in healthy individuals.

Eddingpharm and FAES FARMA to Set Up a Joint Venture in China

June 8, 2015: FAES FARMA and EDDINGPHARM have announced the signing of an agreement to create an equal joint venture for the commercialization of the products of FAES FARMA in the Chinese market.

The project starts with four of the company's products which shall compete in a market valued at 500 million Euros in their market segments. The products shall be manufactured in FAES FARMA plants and exported to China as finished products. Progressively, other FAES products will be incorporated.