CHINA'S LIFE SCIENCE INDUSTRY 10-12/16

Dear Friends and Colleagues,

Over a year ago, the CFDA launched a probe requiring pharmaceutical companies to conduct "self-examination" prior to the audit of their local drug registration submissions. 1,622 applicants were required to attest for their submissions' authenticity and their meeting of standards. As a result, an overwhelming 83% of the probed submissions were voluntarily withdrawn without facing punishment. Of the remaining submissions, 117 were audited by Sep. 2016, of which 30 submissions were rejected on the grounds of authenticity defects.

While the results of the above probe are disconcerting in terms of the quality of local clinical practices ("GCP"), the quality of new drug applications and worse so, in terms of the quality of some marketed drugs, they also indicate the progress the local regulator has made from covering to exposing malpractices and in shifting the emphasis from quantity to quality.

These are also good news for those new drug applicators who are holding solid data to back their submissions: the increasing scrutiny on part of the CFDA is expected to reduce the number of new, fraudulent drug submissions. Coupled with the CFDA's recently announced reforms to fast-track new drug applications, it can be estimated that the assessment process for new quality drugs will become much less time consuming, to the benefit of all stakeholders.

With this positive note, we would like to take the opportunity and wish you and your loved ones a Happy Hannukah, Christmas, New Gregorian Year as well as New Chinese Year of the Rooster! **新年快乐!**

Eyal Harel

CEO-Global

NEWS FROM THE INDUSTRY

Oramed Signs Licensing and Investment Agreements for up to $50 Million

Oramed Pharmaceuticals Inc., a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, announced on Nov. 30, 2015 that it has signed definitive licensing and investment agreements valued at up to $50,000,000 with Hefei Tianhui Incubator of Technologies ("HTIT") for exclusive rights to market Oramed's oral insulin capsule, ORMD-0801, in China, Hong Kong and Macau.

BioAtla and Sinobioway Complete Selection of First Four Programs for Strategic Collaboration in China

BioAtla LLC, a global biotechnology company focused on the development of Conditionally Active Biologic (CAB) antibody therapeutics, announced on December 6, 2016 that together with Beijing Sinobioway Group Company, Limited, they have selected the first four CAB product programs for development. The specific program candidates and the targeted indications were not disclosed. As a result, BioAtla received on November 1, 2016 a $36 million payment from Sinobioway. Including these funds, BioAtla has received more than $100 million in program payments and equity investments relating to its strategic collaboration agreement with Sinobioway.

Spineway Signs a Partnership Agreement with Tinavi Medical Technologies

Spineway, a specialist in implants and surgical instruments for treating spinal column disorders, on September 22, 2016 signed a 5-year partnership agreement with Tinavi Medical Technologies (China) for distributing the group's implant ranges. This partnership is linked to a planned strategic investment by Tinavi in Spineway's equity.

JHL Biotech and Aslan Pharmaceuticals Partner on Manufacturing Services

Nov. 14, 2016. Aslan Pharmaceuticals, a biotech company focused on the development of immunotherapies and targeted agents for tumor types prevalent in Asia, and JHL Biotech, Asia's premiere provider of contract manufacturing services for biologics, have announced a manufacturing services partnership. In accordance with the partnership agreement JHL will provide process development services to Aslan for the continued development of its ASLAN004 programme. Aslan will work with JHL to perform process development and manufacturing of ASLAN004, a fully human monoclonal antibody that blocks the signalling of the IL-4 and IL-13 receptors.

Suda Ltd and Eddingpharm Enter Licensing Agreement for Zolpimist in China

On 9 November 2016, Suda Ltd, a leader in oro-mucosal drug delivery, and

Eddingpharm (Asia) Macao Commercial Offshore Limited, a leading Chinese pharmaceutical company, announced that the companies have entered into an exclusive license agreement for the development and commercialization of Suda's novel ZolpiMist™ oral spray of zolpidem tartrate to treat insomnia in China. Once approved by the CFDA, ZolpiMist would be the first imported fast-acting oral spray of zolpidem tartrate available in China.

Under the terms of the agreement, Suda receives an upfront cash payment of US$300,000 and is entitled to receive a further milestone payment of US$200,000 following registration of the product in China. In addition, once Zolpimist is registered for sale in China, Suda will receive escalating tiered royalties on net sales in the territory. The total value of the deal could exceed US$26 million.

Pluristem's $30 Million Equity Funding Approved by Innovative Medical Management

Israel-based Pluristem Therapeutics Inc., a leading developer of placenta-based cell therapy products, announced on November 10, 2016 that its previously signed and announced term sheet for an investment of approximately $30,000,000 by China-based Innovative Medical Management Co., Ltd., has been approved by Innovative Medical's Board of Directors and its shareholders. As a result of these approvals, the term sheet is now a binding agreement.

The US FDA Granted Orphan Drug Designation to Yisheng Biopharma's Biological Product for Hepatocellular Carcinoma

The U.S. Food and Drug Administration has granted orphan drug designation for the lead product candidate, YS-ON-001, of Beijing-based Yisheng Biopharma, a biopharmaceutical company focusing on research, development, manufacturing, sales and marketing of immuno-therapeutic products and vaccines. The drug for the treatment of hepatocellular carcinoma is a promising biological product with immunomodulating effects, such as the induction of anti-tumor cytokines, the activation of NK cells, the regulation of macrophage polarization, and the suppression of regulatory T cells.

Bispecific Signs Antibody Agreement with EpimAb

Oct. 11, 2016. Kymab Limited, a leading human monoclonal antibody biopharmaceutical company, and EpimAb Biotherapeutics, Inc., an emerging biopharmaceutical company specialising in bispecific antibodies, announced a cross-licensing and development agreement to develop bispecific therapeutic antibodies against multiple targets.

The parties will focus their efforts on immuno-oncology and will combine antibodies sourced from Kymab's proprietary Kymouse™ platform with EpimAb's proprietary Fabs-In-Tandem Immunoglobulin (FIT-Ig™) platform to generate multiple bispecific antibodies.

Kymab will have the development and commercialization rights to these bispecifics in all geographical regions outside of China, and, under the terms of the cross-license agreement, EpimAb will have the rights to the Chinese market.

3SBio closes a $100 Million licensing Agreement with AstraZeneca

On October 11, 2016, Hongkong Sansheng, a wholly-owned subsidiary of 3Sbio entered into an exclusive license agreement with AstraZeneca. Pursuant to the agreement, AstraZeneca has agreed to grant an exclusive license in China to Hongkong Sansheng for the commercialization of AstraZeneca's Byetta, an injectable Glucagon-Like Peptide-1 receptor agonist (GLP-1 RA); and Bydureon, an extended-release formulation of exenatide, administered once weekly as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Hongkong Sansheng has agreed to pay an upfront payment of US$50,000,000 and milestone payments of up to US$50,000,000 to AstraZeneca.