



## CHINA'S LIFE SCIENCE INDUSTRY 02-05/15

Dear Friends and Colleagues,

Recently, we've been witnessing a growing trend to include China as a strategic component in the global clinical development of new drugs. The recent case of CASI Pharmaceuticals showcases the advantages of conducting parts of the global clinical development in China. In addition to potential cost-savings associated with running a clinical program or parts of it in China, such a move provides a significant advantage in terms of the local registration of the new drug. By meeting global as well as local regulatory standards, a successful trial in China can be of significant help in overcoming Chinese regulatory hurdles and save years in terms of time-to-market. Taking into consideration the fact that China is the fastest growing and second largest health market in the world, this translates into significant earnings in the last years of sales of the product in China, otherwise lost due to its late introduction.

I am happy to inform you that we have recently launched XinTech's updated [website](#), which is now available for your convenience in English, German and Chinese.

Sincerely,

Eyal Harel

CEO-Global

### **POLICY RELATED NEWS**

#### ***China Lifts Regulatory Controls on Most Drug Prices***

Chinese regulators say they will lift price controls on most medical drugs starting June 1, 2015 in hopes that a more market-driven pricing system will keep medical costs in check.

The National Development and Reform Commission announced Tuesday that it would abandon a

decades-long practice, which had applied to all drugs except for narcotics and some psychological medication, as part of a drug price reform. This move is expected to encourage local as well as global drug developers to launch more products into the Chinese market. However, uncertainties remain, as power is shifting from China's central government to its many local governments where drug makers still

have to undergo provincial bidding systems.

#### **NEWS FROM THE INDUSTRY**

##### ***CFDA Approves IND for D-Pharm's Anti-Epileptic Drug in China***

On April 14<sup>th</sup>, 2015 D-Pharm Ltd. announced that the Israeli company and its co-development partner Jiangsu Nhwa Pharmaceutical Co., Ltd. had received an approval letter from the Chinese Food and Drug Administration allowing clinical development through Phase 3 for DP-VPA, an epilepsy treatment drug.

Prior to the IND approval, DP-VPA was granted Fast Track Status, a designation designed to bring important new drugs treating serious or life-threatening conditions and filling unmet medical needs to patients more quickly.

##### ***Resverlogix and Hepalink Announce a Licensing and Equity Arrangement***

On Apr 27, 2015, Resverlogix Corp. announced that it has entered into a framework agreement with Shenzhen Hepalink Pharmaceutical. The agreement includes an equity investment of over \$40 million and a license of RVX-208 for China, Hong Kong, Taiwan and Macau.

Total sales-based milestones and royalty payments are estimated to be in excess of \$400 million.

##### ***Fosun Pharma, HOPU Investments, CEL Healthcare Fund and WuXi PharmaTech to Jointly Acquire U.S.-based Ambrx***

A consortium consisting of entities affiliated with the Shanghai Fosun Pharmaceutical Group, HOPU Investments, China Everbright Limited's healthcare fund and WuXi PharmaTech announced on May 21, 2015 that the consortium has signed a merger agreement pursuant to which it will acquire Ambrx Inc.

The transaction is expected to be closed in the second quarter of 2015, subject to certain regulatory approvals and the satisfaction of customary closing conditions.

Ambrx is a clinical-stage biotechnology company focused on discovering and developing first-in-class and best-in-class optimized protein therapeutics known as bio-conjugates. The company's proprietary technology platforms enable attachment of pharmaceutically active molecules to specific sites within proteins more precisely than prior generations of bio-conjugates and with precision similar to that used to design small-molecule drugs.

##### ***Hengrui to Collaborate With MabSpace on Novel Antibody Therapeutics***

May 19, 2015. MabSpace Biosciences Co., Ltd. and Jiangsu Hengrui Medicine Co., Ltd have announced their

collaborative contract to co-develop novel antibody therapeutics on two targets.

According to the agreement, MabSpace will be responsible for the discovery and selection of humanized lead antibodies, while Hengrui will hold exclusive global rights on the resulting therapeutic candidates for the nominated targets, and will further develop the selected candidate molecules.

### ***TVM Capital Announces Initiation of Investment Operations of China Biopharma Capital I VC Fund***

TVM Capital Life Science announced on April 13, 2015 that it has achieved the first closing of China BioPharma Capital I at US \$50 Million. China BioPharma Capital I is a venture capital fund with subscription from Chongqing Lummy Pharmaceutical Co., Ltd. a pharmaceutical company based in Chongqing, China, which develops, manufactures and markets pharmaceuticals and health care products.

### ***BioLight Announces Strategic Partnership to Expand Presence in China***

On April 2, 2015 BioLight and Rock-One International Holdings Ltd announced their strategic partnership. Rock-One is a holding company specializing in investment activities, including in the high tech and biomedical industries. The

agreement will help BioLight maximize its presence in the Chinese market.

Under the terms of the agreement, BioLight will issue a private placement of ordinary shares to Rock-One, which will account for approximately 19% of BioLight's issued capital for approximately \$6.2 million.

As part of the strategic partnership, the parties will also form a joint venture. The newly formed JV will be fully financed by Rock-One and granted exclusive manufacturing rights for BioLight's products distributed in China. The JV will also promote collaboration between Chinese and Israeli academies to develop future products.

### ***Luye Announces Completion of Phase I Clinical Studies of Ansofaxine Hydrochloride Extended Release Tablets (LY03005) in China***

Luye Pharma Group Ltd. announced on March 27, 2015 that the Group has officially completed three phase 1 clinical studies for ansofaxine hydrochloride extended release tablets ("LY03005") in China. The objective of these clinical studies was to evaluate the safety and pharmacokinetic profiles of LY03005 following single or multiple doses of oral administration. A total of 132 healthy subjects were enrolled for these clinical studies

LY03005 is a key central nervous system product candidate being concurrently developed for the Chinese and international market, and is currently undergoing phase I clinical trials in the United States as well.

It is expected to be approved as a Class I “New Chemical Drug” for the treatment of major depressive disorders.

### ***HMP’s Positive fruquintinib POC Study Triggers Payments from Lilly***

Hutchison Medipharma announced on May 13, 2015 that it is set to receive a total of US\$18 million in payments from Eli Lilly and Company (Lilly). The payments have been triggered by the positive results of the first proof-of-concept (POC) study for fruquintinib in the treatment of patients with metastatic colorectal cancer (mCRC) in China. Fruquintinib, a novel selective inhibitor of the Vascular Endothelial Growth Factor (VEGF) receptor tyrosine kinases, was discovered by HMP.

### ***CASI Pharmaceuticals Receives Approval From CFDA For Phase II Clinical Trial In China***

March 30, 2015. CASI Pharmaceuticals has announced the China Food and Drug Administration’s (CFDA) approval to conduct a Phase 2 global clinical trial in ovarian clear cell carcinoma (OCCC) patients for its

proprietary drug candidate ENMD-2076.

The approval will allow CASI to expand its ongoing Phase 2 OCCC trial currently underway in multiple centers in North America. This is the company’s third approval of a global Phase 2 clinical trial in China.

### ***Sirona Announces Positive Preclinical Toxicology Results for its SGLT2 Inhibitor in China***

On March 4, 2015, Sirona Biochem Corp. announced that Wanbang Biopharmaceuticals has successfully completed the toxicology study in the pre-clinical validation of its anti-diabetic SGLT2 Inhibitor SBM-TFC-039 for the treatment of Type 2 diabetes.

The results of the study demonstrated that the maximum tolerated dose (MTD) of SBM-TFC-039 was greater than 800 mg/kg/day, which was significantly greater than the 300 mg/kg/day of the Canagliflozin reference. There was no mortality in the groups treated with SBM-TFC-039 and the histopathology showed no visual abnormalities.

The reference drug Canagliflozin is Johnson and Johnson’s SGLT2 inhibitor for type 2 diabetes. It was the first SGLT2 inhibitor launched and it has been on the market in many countries, including the United States, since 2013.

***Amarin and Eddingpharm  
Announce Agreement to Develop  
and Commercialize Vascepa(R)  
(icosapent ethyl) in China***

February 26, 2015. Amarin Corporation and Eddingpharm have entered into an exclusive agreement for Eddingpharm to develop and commercialize Vascepa® (icosapent ethyl) in China, the Hong Kong and Macao Special Administrative Regions and Taiwan.

Under the agreement, Eddingpharm will be responsible for development and commercialization activities. Amarin will provide development assistance supply the finished product. Terms of the agreement include up-front and milestone payments to Amarin of up to \$169.0 million, including a non-refundable \$15.0 million up-front payment and development, regulatory and sales-based milestone payments of up to an additional \$154million. Eddingpharm will also pay Amarin royalties on net sales of Vascepa. Amarin will supply the product to Eddingpharm under negotiated supply terms.