



## CHINA'S LIFE SCIENCE INDUSTRY 4-5/11

Dear Friends and Colleagues,

It gives us great pleasure to announce the successful closing of the agreement between D-Pharm and Nhwa Pharma Corporation for the licensing and co-development of D-Parm's DP-VPA drug candidate for the treatment of epilepsy.

The deal, which includes Nhwa's commitment to conduct full clinical trials in China under FDA protocol, is worth the equivalent of \$10s millions in clinical developments costs and includes upfront, milestone and royalty payments as well.

Moreover, this transaction allows D-Pharm to concentrate on its flagship product, the b-99 for the treatment of ischemic stroke (Phase III clinical trial), while progressing – at the same time and at almost no additional cost – its second pipeline drug candidate.

This transaction reemphasizes the growing opportunity and mutual benefit Israeli and Chinese life science companies can draw from strategic collaborations.

We wish you all a happy Shavuot/Dragon-Boat Festival!

  
Eyal Harel  
Co-CEO

### **POLICY**

#### ***China Ramps-up its Regulatory Capabilities for Evaluation of New Drugs***

In a recent policy release, "Notice on issuing principles and procedures for technical evaluation of drugs," the China SFDA Center for Drug Evaluation (CDE) highlighted major changes including a restructuring which creates a team of reviewers focused on innovative/new-to-China drugs and which groups evaluators by technical expertise rather than therapeutic area. The policy also specifies that new drugs will receive

simultaneous review by different departments while others will undergo a slower serial evaluation process. The changes clearly aim to markedly reduce approval times for new products while pushing generics to the sideline.

### **INDUSTRY**

#### ***First Chinese Company to Launch Drug in the US***

On May 4, 2011, Beijing Second Pharmaceutical (BSPC) announced (May 4, 2011) that it received US FDA marketing approval for its amlodipine

besylate product, making it one of first Chinese-owned pharmaceutical companies in a position to launch a in-house-developed FDA-approved finished formulation in the US market.

The amlodipine product will be sold in the US via a distribution partner.

### ***Sinovac Announces Success for Phase I Trial of EV71 Vaccine***

May 25, 2011. Sinovac Biotech reported positive results from a Phase I trial of its vaccine for human enterovirus 71 (EV71), the virus that causes Hand, Foot, and Mouth Disease (HFMD). The trial was approved by SFDA and started last December with 168 subjects including adults, children and infants. The phase II trial will be conducted within 1-2 months.

### ***BeiGene Lands Large Investment from Merck***

May 2, 2011. BeiGene, a Beijing startup that focuses on the development of oncology drugs, announced an initial investment from Merck today. The exact size of the investment was not disclosed. There are 5 cancer drug candidates in BeiGene's pipeline, two me-better drugs and three with new mechanisms of action.

### ***Chongqing Zhifei Bidding to Buy Dutch Vaccine Company***

May 13, 2011. Chongqing Zhifei Biological Products entered the auction for Bilthoven Biologicals, a Dutch company offering both vaccines and CMO services, bidding US\$93 million. Bilthoven is a spinoff of the Netherlands Vaccine Institute. Its assets include sophisticated biological product equipment and several

vaccine products. This non-binding offer expects confirmation from Bilthoven Biologicals before August 2011. Zhifei is a public company listed at the Shenzhen Stock Exchange with a market cap of 11 billion RMB.

### ***SciClone to Acquire NovaMed Pharma for ~\$62 Million***

April 19, 2011. SciClone Pharmaceuticals of California has acquired Shanghai-based NovaMed Pharmaceuticals, a privately held company, for a price of ~\$62 million. NovaMed is engaged in clinical development, registration and marketing of western drugs that are not yet launched in China and has collaborated with MNCs for their drugs' launching in China. SciClone, though a US company, has its main market in China, which accounts for more than 90% of its annual sales.

### ***Kinex Licenses China Rights for Cancer Molecule to Hanmi Pharma***

April 21, 2011. Kinex Pharmaceuticals, a New York State based, privately held pharma company, has out-licensed China rights for its lead molecule, KX01, to Hanmi Pharmaceutical Co. of South Korea. KX01 has completed a Phase I trial for end-stage cancer in the US, where it showed a clinical response in 25% of the patients. Hanmi has rights to KX01 in China and other selected Asian countries for all oncology indications. Financial terms were not disclosed.

### ***Dainippon Sumitomo Enters into a Licensing Agreement for a Treatment for Chronic Liver Disease***

March 30, 2011. Dainippon Sumitomo has entered into an exclusive licensing agreement with Intercept Pharmaceuticals for the development and commercialization of the latter's obeticholic acid, a first-in-class FXR agonist for the treatment of chronic liver diseases in China and Japan. Under the terms of the agreement, Intercept will receive an initial payment of \$15 million from DSP and will be eligible to receive approximately \$300 million in additional milestone payments associated with the successful development and commercialization of the drug.

New York City-based Intercept Pharmaceuticals, Inc. is a clinical stage biopharmaceutical company focused on developing small molecule drugs for the treatment of chronic liver and metabolic diseases.

### ***New U.S.-China Drug Development Company Announces Huge Investment***

April 6, 2011. Ascletis, Inc., a US-China biopharma startup, announced a huge \$100 million Series A round, led by Hangzhou Binjiang Investment Holding Co. Initially, Ascletis will in-license promising clinical-stage molecules for cancer and infectious diseases, which it will take to China for development and sales.

The company plans to license promising drug compounds from U.S. and European companies and develop them for the Chinese market. It will focus on cancer and anti-inflammatory drugs.

### ***Kang Sheng Bao to Develop Immune System Diagnostic Test for SuperNova***

March 30, 2011. Shenzhen Kang Sheng Bao Bio-Technology (KSB) has signed an agreement with SuperNova Diagnostics, a Washington DC development stage company, giving KSB the China rights to develop, manufacture and market its diagnostic products that measure neopterin, which is a biomarker of immune system activity.

### ***Zhejiang Hisun Pharma Invests in US Biotech Startup***

March 25, 2011. Zhejiang Hisun Pharma will invest \$6 million in Photolitec LLC, a cancer startup located in Buffalo, NY. Hisun committed to paying Photolitec an upfront of \$2 million and additional \$1 million each year for the next four years, plus milestones. The deal gives Hisun the right of first refusal for compounds being developed in conjunction with Photolitec's Photodynamic Therapy for oncology.