2016 China BioMed Innovation and Investment Conference

Promoting biomedical innovation in China

With the world's largest population, China is one of the biggest drug producers and most promising pharmaceutical markets in the world. Yet the Chinese pharmaceutical industry is often criticized for its lack of innovation, and it is still relatively small despite growing rapidly. Low investment in new drug discovery is frequently blamed for this state of affairs.

Seeking to bring together the Chinese pharmaceutical industry and the capital market for promoting biomedical innovation, the China Pharmaceutical Innovation and Research Development Association (PhIRDA), in collaboration with the Securities Association of China (SAC), co-organized the first China BioMed Innovation and Investment Conference (CBIIC) in November 2016. Held in Suzhou, the conference brought together pharmaceutical enterprises, investment institutions, research institutes and policy makers to discuss the development of China's biomedical industry, trends in new drug R&D, and the investment and policy environments. It provided a rare opportunity for cross-industry exchanges.

In the opening speech, PhIRDA Executive President Ruilin Song noted that China has developed 24 class-1 drugs since 2008, when the Major New Drug Research and Development Project (funded by the Chinese Ministry of Science and Technology) was implemented. "Yet we still have a long way to go to become a powerhouse of biomedical innovation," said Song. "Integrating biomedical innovation with the capital market is essential for the success of this great endeavour."

Policy reform

The development of biopharmaceutical industry needs policy guidance. Currently, China suffers from low-quality drugs, duplicated drug production and repetitive reviews of generic drugs, according to Xianze Sun, vice minister of the China Food and Drug Administration (CFDA). "The reform of the drug review and approval system seeks to improve drug quality, lower prices and encourage drug innovation to benefit social wellbeing," Sun said in his keynote address. Measures are being taken to accelerate the review and approval process, redefine new drugs, re-evaluate the quality and effectiveness of generic drugs, and separate marketing and manufacturing authorization to promote research innovation. Sun also emphasized that pharmaceutical enterprises are the main gatekeeper for ensuring drug safety and the main force for new drug innovation. "With our concerted effort, we will soon shift from 'made in China' to 'innovated by China'," Sun said positively.

Siyuan Zhou, deputy director of the Centre for Drug Evaluation (CDE), CFDA, described current progress in the reform of the drug review and approval system. The main goal is to clear the huge backlog of unprocessed applications, most of which are for clinical trials of generic drugs. Thanks to simplified procedures, CFDA now processes more than 1,000 applications per month on average and has cleared much of the backlog. The reform has also prioritized the review of innovative drugs, drugs for urgent clinical needs, paediatric drugs, patent-expired drugs and domestic first generic drugs to facilitate their quick

entrance into the market. Additional reforms include introducing third-party expert review, optimizing organizational management system and enhancing team building. "We need to set up guiding principles and establish an internationally accepted standard system," said Zhou. "We want to make our centre an authoritative drug evaluation institution that is internationally recognized."

Investment environment

Investors also emphasized the key role of an effective regulatory system in new drug R&D. Currently, China is improving significantly in gathering talented groups and reforming regulatory systems, said Yuan Tian, founding partner of Yuanming Capital. But China still lacks a sound financing system and a fully developed pharmaceutical market for building a healthy investment ecosystem for drug innovation. Tian suggested developing diversified investment bodies to finance drug companies at different stages of R&D. "China is not short of capital," said Tian. "We need to channel the floating capital to drug R&D." For this, a price evaluation system based on the knowledge of the life sciences is needed to guide investors and to break the regional fragmentation of Chinese drug market, according to Tian.

Value-based pricing is becoming a core concept in the global biopharmaceutical market, said Philip Ross, managing director of J. P. Morgan Healthcare Investment Banking, who brought an international perspective to Chinese investors. Healthcare has been among the best performing sector in the investment market, and the biotech industry has always been an outstanding performer, according to Ross. Conditions for merger and acquisition remain strong, and acquirers are increasingly aggressive in buying preapproval assets, with oncology being the most active therapeutic area. Ross emphasized that emerging markets, particularly China's, are a key contributor to global economic growth.

New progress in innovative drugs

The Chinese government has invested around 13.6 billion RMB for the development of major new drugs. This sum was complemented by about 20 billion RMB investment from local governments and enterprises, according to Kaixian Chen, academician of the Chinese Academy of Sciences and vice chairman of the General Expert Committee of National Science

and Technology Major Project for Major New Drug Research and Development. Reviewing the development of the Chinese pharmaceutical industry, Chen was confident of its potential for growth because of emerging promising trends, including increased R&D investment, an improved and standardized preclinical evaluation system, rising medium and small enterprises and the narrowing gap between top Chinese enterprises and international pharmaceutical companies. "With the improved policy environment," said Chen, "China's new drug discovery is expected to achieve a great leap forward in the next five years."

In the session on clinical-trial data release–a highlight of the conference–participating Chinese pharmaceutical enterprises shared exciting progress in new drug discovery. In particular, Sichuan Jiuzhang Biological Science and Technology Company, under the leadership of its chairman of the board, Jie Zhang, pioneered the application of chlorogenic acid for treating cancer and autoimmune diseases. Phase 1 clinical trial with late-stage glioma patients showed significant clinical efficacy with little side effects for this typically deadly brain tumour. "We are now looking into developing chlorogenic acid for intravenous, instead of muscle injection and are expanding the clinical trials," introduced Wenbin Li, chief of the Glioma Department at Beijing Shijitan Hospital, who led the clinical trial study.

Several other companies also introduced their new drug R&D projects. Hua Medicine has developed a glucokinase activator that has a new chemical structure. It exhibits excellent pharmaceutical kinetics properties and achieves sustained efficacy in decreasing blood glucose. Therapeutic areas of other products range from hepatitis C to chronic kidney disease and disorders of the central nervous system.

"New drug discovery benefits the health and wellbeing of all humanity," said Xiang Wang, vice mayor of Suzhou. "It also contributes to socioeconomic development." Wang mentioned that Suzhou Industrial Park has already attracted nearly 500 biomedical companies, producing an annual output of around 50 billion RMB. The industrial park has also become a regular site for CBIIC to further explore financing biomedical innovation. "We are expecting to see deeper partnerships between our participants when we gather here next year," said Song confidently.

New breakthrough in antitumor drug

A new era of therapy has dawned for high-grade glioma patients thanks to an injectable form of chlorogenic acid developed by Jiuzhang Company. A natural compound found in a variety of plants, chlorogenic acid is known for its antioxidant and antibacterial effects and is also associated with lowering blood sugar levels. However, it is difficult to produce in large amounts and its association with respiratory allergy has been a concern.

Inspired by the ingredients of a traditional Chinese medicine, Jie Zhang has been investigating chlorogenic acid since 2000. "It's green and safe," said Zhang, "I'm intrigued by its low toxicity and high antitumor efficacy." Years of effort coupled with large investment led to the successful extraction of high-purity chlorogenic acid from plants. Zhang's team also solved the sensitization issue and obtained soluble chlorogenic acid for medical use.

A small-molecule compound, chlorogenic acid can pass through the blood–brain barrier and induce cell differentiation, thereby turning tumour cells into healthy cells. "It works through the human immune system and has the potential to work well with PD-1 checkpoint inhibitor," said Xiaoguang Chen from the Institute of Materia Medica, Chinese Academy of Medical Sciences, who conducted a pharmacodynamic study for Zhang.

"I'm grateful for the support of Dr. Chen and Dr. Li," said Zhang, "The industry–research–clinical service partnership is essential for the new drug R&D". The collaboration continues as the team explores therapies for other malignant tumours.