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Emerging Company Profile

CANbridge: A bridge to China

By Erin McCallister
Senior Editor

Many small biotechs in the U.S. and Europe do not have the resources to develop their programs in China in parallel with Western territories, leading to a five- to eight-year lag before a Chinese launch. **CANbridge Life Sciences Ltd.** plans to in-license candidates from these companies for China and elsewhere in East Asia as part of a global development strategy for its biotech partners.

CANbridge wants to get the programs to patients in China faster and believes its executive team can help small biotechs develop their programs in China in parallel with an in-house Western development program.

Two of CANbridge's executives have experience taking programs through the clinic and to market in China from time spent working at Genzyme China, a division of **Genzyme Corp.**, which was acquired by **Sanofi** in 2011.

CEO James Xue was the founding general manager of Genzyme China. Crystal Xu, head of clinical development, was Genzyme China's director of medical and regulatory affairs.

Xue established Genzyme's headquarters in Shanghai and led the company's commercial and development efforts in

CANbridge Life Sciences Ltd.

Beijing, China

Technology: N/A

Disease focus: Cancer, rare disease

Clinical status: Phase I

Founded: 2012 by James Xue

University collaborators: Peking University

Corporate partners: Azaya Therapeutics Inc.

Number of employees: 10

Funds raised: Not disclosed

Investors: Angel investors

CEO: James Xue

Patents: 1 issued covering protein stabilized liposomes for the formulation of pharmaceutical agents

China.

He helped get three drugs through development and onto the market in China: Cerezyme imiglucerase for Gaucher's disease; Thymoglobulin anti-thymocyte globulin for anemia and transplant; and Synvisc hylan G-F 20 for osteoarthritis.

"This progress can't be achieved with-

out deep understanding of the products and deep understanding of regulatory review — we have that," Xue said.

While Xue acknowledges that part of the reason for the lag in Chinese approvals and launches is due to a bottleneck at **CFDA**, he believes his experience working with Chinese regulatory authorities as well as patient groups could help to shorten timelines.

"At Genzyme we were able to achieve these approvals not only because of our good relationship with CFDA, but also because we were able to articulate the unmet need of the Chinese patient and use resources from the physician community and patient community to advocate," Xue said.

Henri Termeer, a CANbridge advisor and former Genzyme chairman, president and CEO, told BioCentury he believes success in China will come down to the depth of experience on the executive team. "Their success is all related to the individual backgrounds and track records. James is extremely effective. He understands what it takes to get a product registered, to the market and to patients," he said.

Unlike some China-based in-licensing companies, CANbridge aims to co-de-

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velop programs with its partners by enrolling patients from China, Taiwan and South Korea in the partners' Phase II and Phase III trials.

"We set up CANbridge with the purpose of helping smaller size biotechs to accelerate and operationalize their development strategy in China and harmonize it with the development strategy in other countries," Xue said.

CANbridge is seeking compounds that have completed Phase I in the U.S. or Europe in indications with high unmet need in China, such as lung cancer.

CANbridge in-licensed its first program in September. The biotech received

exclusive rights to **Azaya Therapeutics Inc.**'s ATI-1123 in China, Taiwan and South Korea.

ATI-1123 is a protein-stabilized nanoparticle (PSN) formulation of docetaxel that has completed Phase I testing in solid tumors in the U.S. CANbridge and Azaya plan to start Phase II in China and the U.S. for non-small cell lung cancer (NSCLC). The exact timeline is not disclosed.

According to Xue, CANbridge will file with CFDA to let China sites join Azaya's Phase II study, "during which we will harmonize the clinical protocol on NSCLC."

CANbridge will fund development and commercialization of ATI-1123 in the licensed territories. Azaya is eligible for milestones and royalties.

Xue said CANbridge is in discussions with at least two other companies and expects to announce deals this half.

"My goal is to have at least two licensing or partnership deals signed each year for the next three to five years," he said.

CANbridge is raising a series A round but wouldn't disclose how much it is seeking.

COMPANIES AND INSTITUTIONS MENTIONED

Azaya Therapeutics Inc., San Antonio, Texas

CANbridge Life Sciences Ltd., Beijing, China

China Food and Drug Administration (CFDA), Beijing, China

Genzyme Corp., Cambridge, Mass.

Sanofi (Euronext:SAN; NYSE:SNY), Paris, France