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Canbridge inks deal with Apogenix to bring targeted brain tumor treatment to China

By Shannon Ellis, Staff Writer

SHANGHAI – Beijing-based Canbridge Life Sciences Inc. is a biotech that seeks to bring Western innovation to Chinese patients who have few if any treatment options. That licensing strategy has led it to sign a deal with Apogenix GmbH, of Heidelberg, Germany, for lead candidate APG101, an onco-immunotherapy targeting the CD95 ligand for a highly lethal and difficult to treat type of brain cancer, glioblastoma multiforme.

A classic licensing deal structure, Canbridge has provided an up-front payment, with the promise of milestones and royalties, in exchange for the technology and rights to develop and commercialize APG101 in China, Hong Kong and Macau. Canbridge signed on for indications beyond glioblastoma as well.

"We are always actively looking for clinical-stage assets from biotechs that hold promise for any unmet medical needs, particularly in the oncology area," said James Xue, chairman and CEO of Canbridge. "Apogenix's lead product, APG101, fits like a glove."

Xue said he first met Apogenix execs at the J.P. Morgan Healthcare Conference in San Francisco and that there was an "immediate attraction based on what we respectively do."

For Xue, developing a treatment for glioblastoma is deeply personal. He lost a close friend and classmate to the deadly brain cancer at the age of 35. And it is not lost on him that the "father of the biotech" industry, Genentech Inc. co-founder, Robert Swanson, also battled the disease, passing away when he was only 52.

"It hits very close to home," said Xue. "My own friend's demise over a year and a half, three brain surgeries, from a very brilliant guy to the end – it is very painful. As soon as I saw [Apogenix's] program, I thought this is something we can join hands together to make a difference and have an impact."

Every year in China roughly 10,000 people are diagnosed with glioblastoma. The five-year survival rate is less than 3 percent, with the mortality rate the third highest, after pancreatic cancer and lung cancer.

The incidence of glioblastoma in China is predicted to grow from 1.75 per 100,000 people in 2014, to 2.05 per 100,000 in 2024, which represents a 17 percent increase.

"The mortality rate of malignant glioma is one of the top 10 among all cancers in China. With very limited treatment options, the outcomes for Chinese patients are even more grim than in the West," said Xue.

In China the current standard of care is surgical resection of the tumor followed by radiation and chemotherapy with temozolomide (TMZ).

TARGETING THE CD95 LIGAND

APG101 is a fully human fusion protein that inhibits the CD95 ligand, a member of the tumor necrosis factor superfamily. By blocking the CD95 ligand, APG101 restores the immune response against tumors and inhibits invasive tumor cell growth.

For patients with a high level of CD95 expression, APG101 has a dual function, Xue pointed out: It can activate and restore immune response to inhibit tumor growth, similar to PD-1 immune therapy, as well as directly inhibit tumor cell migration.

Last year, Apogenix completed a phase II trial for APG101 in Europe as a second-line treatment after TMZ chemotherapy or radiation, or both. In that study, CD95 patients increased overall survival by 2.5 times, from 6.5 months to 16.1 months. (See *BioWorld Today*, Jan. 14, 2014.)

Xue said Canbridge will also develop a diagnostic test to identify a certain biomarker associated with CD95 that will be crucial for identifying Chinese patients who benefit most from the treatment. It will also be important for uncovering whether ethnically Chinese patients show any difference; that is not expected to be the case, but no such study on Chinese patients has been conducted to date.

The biomarker will then be later used to develop a companion diagnostic for prediction of therapeutic effect.

Celldex Therapeutics Inc., of Hampton, N.J., also has a targeted therapy for glioblastoma that recently turned

up encouraging results, but Xue said, "It is from a different biomarker, a different slice of the patient tumor, not overlapping with this one so they can be complementary to each other rather than competing." (See *BioWorld Today*, June 2, 2015.)

In China, Xue is hopeful that given the lack of treatment options and the significant unmet need, Canbridge's investigative new drug application will be granted expedited "green channel" status by the CFDA. The firm will also seek to have discussions with the Center for Drug Evaluation to have APG101 considered as a first-line treatment. Xue said he hopes to make a case based on the encouraging results from the phase II trial in Europe.

Canbridge has a heavy hitter in the form of advisor Henri Termeer, former chairman and CEO of Genzyme Corp. "Together, Canbridge and Apogenix can move this exciting program forward more effectively than either could alone in China," Termeer said.

APG101 is the Canbridge's third publicly announced deal, all for cancer-related therapies. Canbridge signed a licensing agreement with Azaya Therapeutics Inc., of San Antonio, for ATI-1123, a liposomal formulation of docetaxel that has completed phase I in the U.S. for non-small-cell lung cancer. (See *BioWorld Today*, Sept. 23, 2013.)

It also is seeking to commercialize Caphosol in China, a treatment approved in developed markets for oral mucositis caused by cancer. That deal was signed with Eusa Pharma Ltd., the international division of Jazz Pharmaceutical plc, of Dublin.

At the end of 2014, Canbridge received $10 million in financing from local venture capital funds Qimng Ventures and TF Capital. (See *BioWorld Today*, Dec. 8, 2014.)