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CANbridge Pharma submits NDA for NERLYNX in China

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CANbridge Pharmaceutical Inc., a biopharmaceutical company developing Western drug candidates in China and North Asia, announced that it has filed a New Drug Application (NDA) to China's National Medical Products Administration (NMPA) for NERLYNX (neratinib) for the extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, following adjuvant trastuzumab-based therapy.

The NMPA has accepted the IND application. NERLYNX was approved in the United States for the same indication in July, 2017 and in the European Union, for the extended adjuvant treatment of hormone receptor positive HER2-positive early stage breast cancer, in September, 2018. CANbridge licensed exclusive development rights to NERLYNX, which CANbridge is developing as CAN030, in greater China (China, Taiwan, Hong Kong and Macao) from Puma Biotechnology, Inc. earlier this year.

"We are very pleased with the progress that CANbridge has made in the regulatory process for NERLYNX in greater China. The fact that CANbridge has so rapidly advanced CAN030, our first Western-approved targeted therapy, along the regulatory pathway in China demonstrates our capacity to bring new medical breakthroughs to China swiftly, where they have the potential to address the unmet needs of millions," said James Xue, PhD, Founder, Chairman and CEO, CANbridge

Pharmaceutical Inc. “HER2-positive breast cancer is on the rise in China, particularly in younger women, and the patient outcomes, with limited current treatment options relative to Western countries, are not as good. We are committed to bringing this important new treatment to these patients, as well as to exploring its potential application in other HER2-positive cancers, such as gastric.”

“We are very pleased with the progress that CANbridge has made in the regulatory process for NERLYNX in greater China,” said Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology. “This is a testament to their dedication to helping breast cancer patients in China. We are very pleased to see this dedication to patients, which helps Puma to recognize its goal of making NERLYNX available to patients worldwide. We look forward to CANbridge’s continued progress in this regulatory process for NERLYNX.”