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Puma Biotechnology and CANbridge Life Sciences Enter into Exclusive Licensing Agreement to Commercialize NERLYNX® (neratinib) in Greater China

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Terms:

Dateline City:
LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, and CANbridge Life Sciences, a biopharmaceutical company focused on developing Western drug candidates in China and North Asia, have entered into an exclusive agreement under which CANbridge will develop and commercialize NERLYNX® (neratinib) in mainland China, Taiwan, Hong Kong, and Macau (greater China).

NERLYNX is not approved currently for commercialization outside of the United States. CANbridge will be responsible for seeking the requisite regulatory approval and, once approved, for commercializing NERLYNX in greater China. Puma will receive an upfront payment of $30 million and potential milestone payments totaling up to $40 million upon achievement of certain regulatory milestones. In addition, Puma will receive significant double-digit royalties on NERLYNX sales in greater China and potential milestone payments upon the achievement of certain sales-based milestones.

“Puma is committed to providing access to NERLYNX to patients around the world, and greater China represents a very large market opportunity,” stated Alan H. Auerbach, Chief Executive Officer and President of Puma. “While we continue to focus our commercial resources on the U.S. market, we believe this new partnership with CANbridge will help patients in greater China to access NERLYNX at the earliest opportunity.”

“We are excited about the opportunity to provide this therapy to patients with HER2-positive cancer in our region,” said James Xue, Ph.D., Chief Executive Officer and President of CANbridge Life Sciences. “We plan to engage our local regulatory authorities in greater China to expedite commercial access to NERLYNX, which we expect to provide in parts of greater China by mid-2019. We are honored to have been selected by Puma to develop and commercialize this important therapy, which we believe has significant commercial potential in greater China in HER2-positive cancers, including gastric cancer, where CANbridge will be leading the clinical development in greater China.”

Neratinib was approved by the U.S. Food and Drug Administration (FDA) in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets.

About HER2-Positive Breast Cancer

Approximately 20% to 25% of breast cancer tumors over-express the HER2 protein. HER2-positive breast cancer is often more aggressive than other types of breast cancer, increasing the risk of disease progression and death. Although research has shown that trastuzumab can reduce the risk of early stage HER2-positive breast cancer returning after surgery, up to 25% of patients treated with trastuzumab experience recurrence.

IMPORTANT SAFETY INFORMATION

NERLYNX ® (neratinib) tablets, for oral use

INDICATIONS AND USAGE: NERLYNX is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early-stage HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea occurring despite recommended prophylaxis with additional antidiarrheals, fluids, and electrolytes as clinically indicated. Withhold NERLYNX in patients experiencing severe and/or persistent diarrhea. Permanently discontinue NERLYNX in patients experiencing Grade 4 diarrhea or Grade ≥ 2 diarrhea that occurs after maximal dose reduction.
- **Hepatotoxicity:** Monitor liver function tests monthly for the first 3 months of treatment, then every 3 months while on treatment and as clinically indicated. Withhold NERLYNX in patients experiencing Grade 3 liver abnormalities and permanently discontinue NERLYNX in patients experiencing Grade 4 liver abnormalities.
- **Embryo-Fetal Toxicity:** NERLYNX can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS: The most common adverse reactions (≥ 5%) were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased and urinary tract infection.

To report SUSPECTED ADVERSE REACTIONS, contact Puma Biotechnology, Inc. at 1-844-NERLYNX (1-844-637-5969) and www.NERLYNX.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch .

DRUG INTERACTIONS:

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors (PPI) and H2-receptor antagonists. Separate NERLYNX by 3 hours after antacid dosing.
- Strong or moderate CYP3A4 inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- P-glycoprotein (P-gp) substrates: Monitor for adverse reactions of narrow therapeutic agents that are P-gp substrates when used concomitantly with NERLYNX.

USE IN SPECIFIC POPULATIONS:

- Lactation: Advise women not to breastfeed.

Please see Full Prescribing Information for additional safety information.

The recommended dose of NERLYNX is 240 mg (six 40 mg tablets) given orally once daily with food, continuously for one year. Antidiarrheal prophylaxis should be initiated with the first dose of NERLYNX and continued during the first 2 months (56 days) of treatment and as needed thereafter.

To help ensure patients have access to NERLYNX, Puma has implemented the Puma Patient Lynx support program to assist patients and healthcare providers with reimbursement support and referrals to resources that can help with financial assistance. More information on the Puma Patient Lynx program can be found at www.NERLYNX.com or 1-855-816-5421.

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses the global development and commercialization rights to three drug candidates — PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib (oral) was approved by the FDA in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

Further information about Puma Biotechnology can be found at www.pumabiotechnology.com.

About CANbridge Life Sciences

CANbridge Life Sciences, Ltd. is a clinical-staged bio-pharmaceutical company accelerating development and commercialization of specialty healthcare products for serious and critical medical conditions in China and North Asia (Korea and Taiwan). CANbridge develops partnerships with Western bio-pharmaceutical companies with clinical-stage pharmaceutical, medical device or diagnostic products that are either unavailable in China/North Asia or address medical needs that are underserved in the region. CANbridge also licenses, or obtains exclusive rights to commercialize, drug and device products that are approved in their home markets for commercialization in China and North Asia. Led and backed by a highly-seasoned executive team, with extensive Chinese drug development experience, CANbridge has the capability to select, acquire, develop and commercialize future therapeutics and diagnostics targeting the unmet medical needs of Chinese and East Asian patients with serious or critical conditions. CANbridge is privately-held and headquartered in Beijing, China.

Additional information can be found at http://www.canbridgepharma.com/.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the commercialization and commercial availability of NERLYNX® in greater China; the registration of, and regulatory approval of, NERLYNX in the region; the expected milestone payments and royalties payable under the agreement with CANbridge; the benefits of NERLYNX and neratinib, including for the treatment of gastric cancer; the Company's clinical trials; and the announcement of data relative to those trials. All forward-looking statements included in this press release involve risks and uncertainties that could cause the Company's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, which include, but are not limited to, the fact that the Company has only recently commenced commercialization and shipment of its only FDA approved product; the Company's dependence upon the commercial success of NERLYNX (neratinib); the Company's history of operating losses and its expectation that it will continue to incur losses for the foreseeable future; risks and uncertainties related to the Company's ability to achieve or sustain profitability; the Company's ability to predict its future prospects and forecast its financial performance and growth; failure to obtain sufficient capital to fund the Company's operations; the effectiveness of sales and marketing efforts; the Company's ability to obtain FDA approval or other regulatory approvals in the United States or elsewhere for other indications for neratinib or other product candidates; the challenges associated with conducting and enrolling clinical trials; the risk that the results of clinical trials may not support the Company's drug candidate claims; even if approved, the risk that physicians and patients may not accept or use the Company's products; the Company's reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates; risks pertaining to securities class action, derivative and defamation lawsuits; the Company's dependence on licensed

intellectual property; and the other risk factors disclosed in the periodic and current reports filed by the Company with the Securities and Exchange Commission from time to time, including the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to update these forward-looking statements, except as required by law.

Language:
English

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