News Release

Puma Biotechnology's Licensing Partner CANbridge Pharmaceutical Submits New Drug Application for NERLYNX® (neratinib) in China

LOS ANGELES, Calif., Oct. 2, 2018 – Puma Biotechnology, Inc. (Nasdaq: PBYI) has been advised that its licensing partner CANbridge Pharmaceutical Inc received confirmation that China's National Medical Products Administration (NMPA) has accepted its New Drug Application (NDA) for NERLYNX® (neratinib) for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer, following adjuvant trastuzumab based-therapy. 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.

James Xue, PhD, Founder, Chairman and CEO of CANbridge Pharmaceutical Inc, said, "The fact that CANbridge has so rapidly advanced CAN030 (neratinib), our first Western-approved target therapy, along the regulatory pathway in China demonstrates our capacity to new bring medical breakthroughs to China swiftly, where they can potentially address the unmet needs of millions. 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. This is a testament to their dedication to helping breast cancer patients in China and we are very pleased to see this dedication to the patients, which helps Puma to recognize its goal of making NERLYNX available to patients worldwide," said Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology. "We look forward to CANbridge's continued progress in this regulatory process for NERLYNX."

About HER2-Positive Breast Cancer

Approximately 20 to 25 percent 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.

About CANbridge Pharmaceutical

CANbridge Pharmaceutical Inc is a clinical-stage 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). The company 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. It 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. CANbridge has exclusive rights to develop and

commercialize Puma Biotechnology's NERLYNX® (neratinib) in China, Taiwan, Hong Kong and Macao (collectively, greater China).

CANbridge is privately-held and headquartered in Beijing, China. Further information may be found at www.canbridgepharma.com.

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. Puma 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 U.S. Food and Drug Administration 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 was granted marketing authorization by the European Commission for the extended adjuvant treatment of hormone receptor-positive HER2-positive early stage breast cancer in September 2018. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

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

Important Safety Information Regarding NERLYNX® (neratinib) U.S. Indication

NERLYNX® (neratinib) tablets, for oral use

INDICATIONS AND USAGE: NERLYNX is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with 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 inpatients 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.

To help ensure patients have access to NERLYNX, Puma has implemented the Puma Patient Lynx support program to assist patients and health care 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.

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

Important EU NERLYNX® (neratinib) Safety Information

All suspected adverse reactions should be reported in accordance with the national reporting system.

The adverse reactions described in this section were identified in the randomized Phase 3 clinical trial (n=2840). The most common adverse reactions of any grade were diarrhoea (93.6%), nausea (42.5%), fatigue (27.3%), vomiting (26.8%), abdominal pain (22.7%), rash (15.4%), decreased appetite (13.7%), abdominal pain upper (13.2%), stomatitis (11.2%), and muscle spasms (10.0%).

The most common Grade 3-4 adverse reactions were diarrhoea (Grade 3, 36.9% and Grade 4, 0.2%) and vomiting (Grade 3, 3.4% and Grade 4, 0.1%).

Adverse reactions reported as serious included diarrhoea (1.9%), vomiting (1.3%), dehydration (1.1%), nausea (0.5%), alanine aminotransferase increased (0.4%), aspartate aminotransferase increased (0.4%), abdominal pain (0.3%), fatigue (0.3%) and decreased appetite (0.2%).

For full European prescribing information, please refer to the NERLYNX (neratinib) Summary of Product Characteristics on the European Medicines Agency website (http://www.ema.europa.eu/ema/).

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding potential indications for NERLYNX and the worldwide expansion of NERLYNX. All forward-looking statements involve risks and uncertainties that could cause Puma'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 risk factors disclosed in the periodic and current reports filed by Puma with the Securities and Exchange Commission from time to time,

including Puma's Annual Report on Form 10-K for the year ended December 31, 2017. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Puma assumes no obligation to update these forward-looking statements, except as required by law.

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