News Release

Puma Biotechnology and Bixink Therapeutics Enter into Exclusive Licensing Agreement to Commercialize NERLYNX® (neratinib) in South Korea

LOS ANGELES, Calif., April. 30, 2020 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, and Bixink Therapeutics, a new South Korean company working in the field of anti-cancer drugs and digital therapeutics, have entered into an exclusive agreement under which Bixink will commercialize NERLYNX® (neratinib) in South Korea.

Bixink will be responsible for seeking the requisite regulatory approval and, once approved, for commercializing NERLYNX in South Korea. Under the terms of the agreement, Puma will receive upfront and milestone payments of up to $6 million, as well as significant double-digit royalties on the sales of NERLYNX in South Korea.

"Our new agreement with Bixink demonstrates our commitment to bringing NERLYNX to patients around the world while continuing to focus our commercial resources on the U.S. market," stated Alan H. Auerbach, Chief Executive Officer and President of Puma. "We are excited about the potential to provide South Korean breast cancer patients with access to NERLYNX."

"We are excited about the opportunity to provide NERLYNX to patients with HER2-positive breast cancer in South Korea and plan to file for its market authorization before the end of 2020," said Dr. Sung Chul Kim, Chief Executive Officer of Bixink Therapeutics. "NERLYNX is our top priority as we aspire to be a leading South Korean company in the field of oncology therapeutics."

Neratinib is approved in the United States for both the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and HER2-positive metastatic breast cancer 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:

- As a single agent, for the extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy.
- In combination with capecitabine, for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer, who have received two or more prior anti-HER2 based regimens in the metastatic setting.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea. If diarrhea occurs despite recommended prophylaxis, treat 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 (reported in ≥ 5% of patients) were as follows:

- NERLYNX as a single agent: Diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increased, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased, and urinary tract infection.
- NERLYNX in combination with capecitabine: Diarrhea, nausea, vomiting, decreased appetite, constipation, fatigue/asthenia, weight decreased, dizziness, back pain, arthralgia, urinary tract infection, upper respiratory tract infection, abdominal distention, renal impairment, and muscle spasms.

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. When patients require gastric acid reducing agents, use an H_2-receptor antagonist or antacid. Separate NERLYNX by at least 3 hours with antacids. Separate NERLYNX by at least 2 hours before or 10 hours after H_2-receptor antagonists.
- Strong CYP3A4 inhibitors: Avoid concomitant use.
- Moderate CYP3A4 and P-glycoprotein (P-gp) dual 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 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. Puma in-licenses the global development and commercialization rights to PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in 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. In February 2020, NERLYNX was also approved by the FDA in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. NERLYNX was granted marketing authorization by the European Commission in 2018 for the extended adjuvant treatment of adult patients with early stage hormone receptor-positive HER2-overexpressed/amplified breast cancer and who are less than one year from completion of prior adjuvant trastuzumab-based therapy. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

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

About Bixink

Bixink Therapeutics Co. Ltd. is a new South Korean company dedicated towards establishing a new treatment paradigm via converging biotechnology and information technology. Currently focused on the field of anti-cancer drugs and digital therapeutics, Bixink will start commercialization of anti-cancer drug NERLYNX® and aims to diligently secure follow up pipeline products, including cancer supportive care and oncologics with novel drug delivery. Bixink also actively seeks various opportunities for collaboration such as co-development and strategic investment to drive its momentum for growth. As one of the pioneers in the field of digital therapeutics in South Korea, Bixink is capable of analysis, R&D, development and validation, and plans to file an Investigational Device Exemption (IDE) with the U.S. Food and Drug Administration by the end of this year to launch its first digitalized cognitive behavioral therapy for obsessive compulsive disorder. In the long term, Bixink strives to create a new path by encompassing medicines and digital therapeutics with better clinical outcomes and cost-effectiveness for patients. Bixink strives to push the boundaries of technology to transform medicine.

To find out more about Bixink Therapeutics, please visit www.bixink-therapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the international 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, any adverse impact on Puma's business or the global economy and financial markets, generally, from the global COVID-19 pandemic, and 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, 2019 and subsequent reports. 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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