



News Release

Puma Biotechnology and Pint Pharma Enter into Exclusive Licensing Agreement to Commercialize NERLYNX® (neratinib) in Latin America

LOS ANGELES, Calif., April 3, 2018 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, and Pint Pharma International S.A., a company focused on innovative treatments for patients in Latin America with cancer, rare diseases, and genetic disorders, have entered into an agreement for Pint Pharma to commercialize NERLYNX® (neratinib) in Argentina, Brazil, Chile, Colombia, Mexico and the rest of Latin America.

NERLYNX is not approved currently for commercialization outside of the United States. Pint Pharma will be responsible for seeking the requisite regulatory approvals and, once approved on a country by country basis, for commercializing NERLYNX in Latin America. Puma will receive an upfront payment as well as potential regulatory and commercial milestone payments totaling up to \$34.5 million. In addition, Puma will receive significant double-digit royalties on NERLYNX sales in Latin America.

“Puma is committed to making NERLYNX commercially available to breast cancer patients around the world,” stated Alan H. Auerbach, Chief Executive Officer and President of Puma. “Our new partnership with Pint Pharm in Latin America demonstrates our commitment to ensure NERLYNX access to patients globally while we continue to focus our commercial resources on the U.S. market. We are confident this new partnership will help patients in Latin America access NERLYNX at the earliest opportunity.”

“We are excited to be collaborating closely with Puma as we plan to file for regulatory approvals of NERLYNX throughout Latin America,” said David Muñoz Guzman, Chief Executive Officer of Pint. “NERLYNX is highly complementary to our comprehensive oncology product offering and it will be the first breast cancer treatment within our portfolio, strengthening Pint Pharma’s presence in the Latin American oncology market. Furthermore, we plan to accelerate patient access to NERLYNX via the various early access programs available throughout the region.”

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 ($\geq 5\%$) 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. NERLYNX® (neratinib) is approved for commercial use by prescription in the United States as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed as NERLYNX. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, the Company is primarily focused on the commercialization of NERLYNX and the continued development of its other advanced drug candidates directed at the treatment of HER2-positive breast cancer. The Company believes that NERLYNX has clinical application in the potential treatment of several other cancers that over-express or have a mutation in HER2.

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

About Pint Pharma

Pint Pharma is a private, Latin American focused pharmaceutical company, devoted to the development, registration and commercialization of specialty based treatments. Pint Pharma benefits from leaders with extensive experience in the pharmaceutical sector and who are based strategically throughout Latin America and Europe. Pint Pharma has a long track record of developing strong relationships with global pharmaceutical and healthcare companies. Pint Pharma strives to be the first Pan-Latin American provider of innovative and high value-added treatments within Oncology, Rare Diseases and Specialty Care.

Additional information can be found at www.pint-pharma.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the commercialization and availability of NERLYNX® (neratinib) in Latin America; the registration and regulatory approval of NERLYNX in the region; the expected milestone payments and royalties payable under the agreement with Pint Pharma; the benefits of NERLYNX and neratinib; 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 Company's dependence on the commercial success of NERLYNX; 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 regulatory approval of NERLYNX outside of the United States; 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; 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 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. The Company assumes no obligation to update these forward-looking statements, except as required by law.

Contact:

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500

info@pumabiotechnology.com

ir@pumabiotechnology.com

David Schull or Amiad Finkelthal, Russo Partners, +1-212-845-4200

david.schull@russopartnersllc.com

amiad.finkelthal@russopartnersllc.com

David R Munoz or Alejandra Pedraza, Pint Pharma International S.A.

office@pint-pharma.ch

Alejandra.pedraza@pint-pharma.com

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