Published on *Puma Biotechnology Investor Center* (https://investor.pumabiotechnology.com) on 1/11/19 5:03 am PST

Puma Biotechnology and Knight Therapeutics Enter into Exclusive License Agreement to Commercialize NERLYNX® (neratinib) in Canada

Release Date:
Friday, January 11, 2019 5:03 am PST

Terms:

Dateline City:
LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced that it has entered into an exclusive License Agreement with Knight Therapeutics Inc. (TSX: GUD) that grants Knight the exclusive right to commercialize NERLYNX® (neratinib) in Canada.

Puma Biotechnology filed a new drug submission for NERLYNX® with Health Canada in July 2018 for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. Under the terms of the License Agreement, Knight will be responsible for all commercial activities and future regulatory submissions for NERLYNX® in Canada. Puma will receive upfront and milestone payments up to $7.2 million USD throughout the term of this agreement, as well as double digit royalties on net sales of NERLYNX in Canada.

“Our new agreement with Knight 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 confident this new partnership will help patients in Canada access NERLYNX at the earliest opportunity.”

“We are excited to partner with Puma to offer a new treatment option to Canadian breast cancer patients," said Jonathan Ross Goodman, Chief Executive Officer of Knight. "While adjuvant trastuzumab-based therapy has been shown to reduce the risk of recurrence in early stage HER2-positive breast cancer, up to 25% of patients treated with adjuvant trastuzumab will have a recurrence. NERLYNX® has been shown to significantly reduce the risk of recurrence in those patients who were previously treated with trastuzumab."

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 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.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding timeframes for regulatory approval and commercialization of NERLYNX in Canada. 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.

Language:
English

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Ticker Slug:
Ticker: PBYI
Exchange: NASDAQ
ISIN:
US74587V1070

Source URL: https://investor.pumabiotechnology.com/press-release/puma-biotechnology-and-knight-therapeutics-enter-exclusive-license-agreement-commercia