News Release

Puma Biotechnology and Pierre Fabre Enter into Exclusive License Agreement to Develop and Commercialize NERLYNX® (neratinib) in Europe

LOS ANGELES, Calif. and CASTRES, France, April 1, 2019 – Puma Biotechnology, Inc. (Nasdaq: PBYI) and Pierre Fabre have entered into an exclusive license agreement under which Pierre Fabre will develop and commercialize NERLYNX® (neratinib) within Europe and part of Africa. In September 2018 the European Commission granted marketing authorization for NERLYNX® (neratinib) 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 the completion of prior adjuvant trastuzumab-based therapy.

Pierre Fabre will have exclusive commercialization rights for NERLYNX in European countries excluding Russia and Ukraine, along with countries in North Africa and francophone countries of West Africa. Pierre Fabre will also be responsible of conducting additional clinical studies and leading regulatory activities in connection with the European Medicines Agency (EMA).

Under the terms of the agreement, Puma will receive an upfront payment of $60 million, as well as additional regulatory and commercial milestone payments totaling up to $345 million. In addition, Puma will receive significant double-digit royalties on NERLYNX sales throughout the territory covered by the license agreement between Puma and Pierre Fabre.

“Puma is committed to providing access to NERLYNX to patients around the world and soon physicians and patients in Europe will have commercial availability of NERLYNX,” stated Alan H. Auerbach, Chief Executive Officer and President of Puma. “Pierre Fabre has a robust commercial and medical oncology infrastructure that we hope will lead to rapid commercial access to NERLYNX.”

“We are thrilled to provide this new therapy to patients with HER2-positive breast cancer throughout Europe,” said Frederic Duchesne, Chief Executive Officer, Pierre Fabre Pharmaceuticals. “Pierre Fabre has developed a strong expertise and presence in the breast cancer treatment and the addition of NERLYNX to our historical oncology portfolio will allow us to strengthen our commercial presence. We anticipate providing access to NERLYNX to patients throughout Europe in 2019 and 2020, starting with Germany.”

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 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/).

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. When

patients require gastric acid reducing agents, use an H2-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 H2-receptor antagonists.

- 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<https://nerlynx.com/pdf/full-prescribing-information.pdf> for additional safety information.

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 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 in September 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 Oncology at Pierre Fabre

Pierre Fabre's expertise in oncology is based on almost four decades of experience in the discovery, development and global marketing of innovative cancer drugs, including monoclonal antibodies and ADCs. Navelbine® has been one of the company's major successes and is valuable in the treatment of breast cancer patients. The company conducts its R&D in two oncology centers, based in Saint-Julien-en-Genevois (near Geneva) and at the Oncopole campus in Toulouse. The Oncopole is officially recognized by the French government as a National Center of Excellence for cancer research. In 2015, Pierre Fabre entered into an agreement with the American biotech company, Array BioPharma, to codevelop two small molecules (kinase inhibitors), Braftovi® & Mektovi®. The primary indication (melanoma) was approved in September 2018 by EMA and marketing is already underway in Germany, the UK, the Netherlands, Austria, Norway and Denmark.

About Pierre Fabre

With a portfolio representing a continuum of activities spanning from prescription drugs and consumer healthcare products to dermo-cosmetics, Pierre Fabre is the 2nd largest dermo-cosmetics laboratory in the world, the 2nd largest private French pharmaceutical group and the market leader in France for products sold over the counter in pharmacies. Its portfolio includes several global brands and franchises among which Eau Thermale Avène, Klorane, Ducray, René Furterer, A-Derma, Galénic, Elancyl, Naturactive, Pierre Fabre Health Care, Pierre Fabre Oral Care, Pierre Fabre Dermatologie and Pierre Fabre Oncologie.

In 2018, Pierre Fabre generated 2.3 billion euros in revenues, of which 63% came from its international business and 61% from its dermo-cosmetics division. Pierre Fabre, which has always been headquartered in the South-West of France, counts about 11,000 employees worldwide, owns subsidiaries and offices in 47 countries and enjoys distribution agreements in over 130 countries. In 2018, Pierre Fabre dedicated 187 million euros to R&D efforts, split between oncology, consumer healthcare, dermatology and dermo-cosmetics.

Pierre Fabre is 86%-owned by the Pierre Fabre Foundation, a government-recognized public-interest foundation, and secondarily by its own employees through an international employee stock ownership plan.

The independent French certification group AFNOR audited in 2015 Pierre Fabre for its corporate social responsibility policy at the "exemplary" level, according to the ISO 26000 standard for CSR.

To find out more about Pierre Fabre, please go to www.pierre-fabre.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the commercialization and commercial availability of NERLYNX® in European countries excluding Russia and Ukraine, along with countries in North Africa and francophone countries of West Africa; the registration and regulatory approval of NERLYNX in the region; and potential payments and royalties payable under the license agreement.. 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, 2018. 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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