News Release

Puma Biotechnology and Pierre Fabre Amend NERLYNX® License Agreement to Include Greater China

Puma Biotechnology and CANbridge Pharmaceuticals Terminate License Agreement in Greater China

LOS ANGELES, Calif. and CASTRES, France, Feb. 25, 2021 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, and Pierre Fabre, a leading French pharmaceutical company, have agreed to extend the terms of the 2019 license agreement which grants Pierre Fabre exclusive rights to develop and commercialize NERLYNX® (neratinib) within Europe, Turkey, Middle East and Africa. The amended agreement extends Pierre Fabre's commercial rights for NERLYNX to Greater China, which includes mainland China, Taiwan, Hong Kong and Macau.

Under the terms of the amendment, Puma will receive an upfront payment of $50 million, as well as additional regulatory and sales-based milestone payments that could add up to an additional $240 million. These milestones will be based solely on regulatory and sales achievements in Greater China. In addition, Puma will receive significant double-digit tiered royalties on the sales of NERLYNX in Greater China.

Concomitantly, Puma and CANbridge Pharmaceuticals, Inc., a biopharmaceutical company focused on developing drug candidates in China and North Asia, have mutually agreed to terminate the license agreement to commercialize NERLYNX (neratinib) in Greater China. Puma has agreed to pay CANbridge a one-time termination fee of $20 million to return all rights to neratinib in Greater China back to Puma. Additionally, Puma has agreed to dismiss the arbitration demand it filed on July 28, 2020 against CANbridge related to the parties' 2018 license agreement, and as part of the settlement, CANbridge has agreed to dismiss its counterclaims against Puma. Such settlement is limited to claims that arose in arbitration, or could have been raised in arbitration, as well as claims arising under the to be terminated license agreement.

Alan H. Auerbach, Chief Executive Officer and President of Puma, said, "We are pleased to extend our collaboration with Pierre Fabre into the Greater China region. Pierre Fabre is well equipped with existing infrastructure to make NERLYNX a success in mainland China and Pierre Fabre plans to make NERLYNX available to breast cancer patients in mainland China in the second quarter of this year."

"We are excited about the opportunity to provide NERLYNX to Chinese patients with early stage HER2-positive breast cancer," said Jean-Luc Lowinsky, Chief Executive Officer, Pierre Fabre Pharmaceuticals. "Our oncology team based in Shanghai is fully committed to start the commercialization of NERLYNX, which perfectly complements our existing NAVELBINE chemotherapy in breast and lung cancers."

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 for adult patients with advanced or metastatic HER2-positive breast cancer in combination with capecitabine in

patients who have received two or more prior anti-HER2 based regimens and is marketed in the United States as NERLYNX® (neratinib) tablets.

About HER2-Positive Breast Cancer

Up to 20% of patients with breast cancer tumors over-express the HER2 protein (HER2-positive disease) and in the ExteNET study, 57% of patients were found to have tumors that were hormone-receptor positive. 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 recurring, up to 25% of patients treated with trastuzumab experience recurrence within 10 years, the majority of which are metastatic recurrences.

About Pierre Fabre

Pierre Fabre is a French health and beauty care company with 35-years of experience in innovation, development, manufacturing and commercialization in oncology. The company has recently reaffirmed oncology as one of its main R&D and commercial priorities, focusing on targeted therapies, biotherapies and immuno-oncology. Its therapeutic areas cover high unmet medical needs, including colorectal, breast, lung cancers, melanoma and pre-cancerous conditions like actinic keratosis.

The Pierre Fabre group has been operating in China since 2008. Based in Beijing, Guangzhou and Shanghai, Pierre Fabre commercializes an anticancer drug, Navelbine, and three dermo-cosmetic brands, namely market-leader Eau Thermale Avène, Klorane and René Furterer. China is the group's first subsidiary after France.

In 2019, Pierre Fabre generated 2.4 billion euros in revenues, of which two-thirds originated from its international business. Pierre Fabre, which has always been headquartered in the South-West of France, employs approximately 10,000 people worldwide, owns subsidiaries and offices in 45 countries and enjoys distribution agreements in over 130 countries. Pierre Fabre is 86%-owned by the Pierre Fabre Foundation, a government-recognised public-interest foundation, and secondarily by its own employees through an international employee stock ownership plan.

In 2019, Ecocert Environment assessed the Group's corporate social and environmental responsibility approach according to the ISO 26000 standard on sustainable development and awarded it the ECOCERT 26000 "Excellence" level.

Further information about Pierre Fabre can be found at www.pierre-fabre.com, @PierreFabre.

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.

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; randomized 1:1 to receive either NERLYNX or placebo). The most common adverse reactions of any grade were diarrhea (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 diarrhea (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 diarrhea (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, U.S. INDICATIONS

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) 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.

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, once filed, Puma's Annual Report

on Form 10-K for the year ended December 31, 2020. 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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