News Release

Puma Biotechnology Presents Interim Results from the Biliary Tract Cancers Cohort of the Phase II SUMMIT "Basket" Trial of Neratinib at ASCO GI

LOS ANGELES, Calif., Jan. 15, 2021 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced interim results from the biliary tract cancers cohort of the ongoing SUMMIT trial of neratinib at the virtual 2021 Gastrointestinal Cancers Symposium hosted by the American Society of Clinical Oncology (ASCO GI) that is currently taking place. The presentation, entitled, "Targeting HER2 (ERBB2) mutation-positive advanced biliary tract cancers with neratinib: Results from the phase II SUMMIT "basket" trial," is being presented at a Poster Session by James J. Harding, MD, Regional Director, Early Drug Development, Memorial Sloan Kettering Cancer Center, an investigator of the trial. A copy of this poster presentation is available on the Puma website.

The Phase II SUMMIT basket trial is an open-label, multicenter, multinational study that included a cohort evaluating the safety and efficacy of neratinib administered daily to patients who have HER2 (ERBB2) mutation-positive advanced biliary cancer. Patients received 240 mg of neratinib daily as a single agent.

In this cohort of 25 patients, 11 patients had cholangiocarcinoma, 10 patients had cancer of the gallbladder and 4 patients had cancer of the ampulla of Vater. 24 patients had received prior systemic chemotherapy with a median of 2 prior lines of therapy (range 0-7) before entering the trial.

The efficacy results from the trial demonstrated that there were 4 patients with confirmed partial responses (3 patients with cancer of the gallbladder and 1 patient with cholangiocarcinoma) and an additional 3 patients who had stable disease lasting ≥16 weeks (1 patient with cancer of the ampulla of Vater and 2 patients with cholangiocarcinoma, one of which remained on treatment for 56 weeks before progression). This resulted in an objective response rate of 16% and a clinical benefit rate of 28%. The durations of response were 3.0 months, 3.7 months, and 4.7 months and additionally one patient with gallbladder cancer remains on treatment >80 weeks.

The safety profile of patients with biliary tract tumors is similar to that previously reported for patients treated with neratinib monotherapy and mandatory loperamide prophylaxis in the first 2 months; treatment was manageable, with 56% of patients experiencing some diarrhea, including 24% with grade 3 diarrhea. There were no episodes of grade 4 diarrhea, and no treatment discontinuations due to diarrhea. Four patients required neratinib dose reduction and one patient was hospitalized due to diarrhea.

"We have shown neratinib to be safe and tolerable in these patients with advanced biliary tract tumors, and demonstrated activity comparable to current standards of care with similar progression-free survival and overall survival in these heavily pretreated patients," said Dr. Harding.

Alan H. Auerbach, CEO and President of Puma Biotechnology, added, "We are very pleased with the preliminary activity seen with neratinib in this cohort of patients and specifically in patients with cancer of the gallbladder and cholangiocarcinoma."

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 may be found at www.pumabiotechnology.com.

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) 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.

Contacts

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

info@pumabiotechnology.com

ir@pumabiotechnology.com

David Schull or Maggie Beller, Russo Partners, +1 212 845 4200

david.schull@russopartnersllc.com

maggie.beller@russopartnersllc.com

# # # # #