News Release

Puma Biotechnology's NERLYNX® Included in Two Important NCCN Clinical Practice Guideline Updates for the Treatment of Breast Cancer

LOS ANGELES, Calif., Jan. 12, 2022 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced that the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines) for the treatment of breast cancer have been updated for 2022 and include two important changes involving neratinib (NERLYNX®).

The first update added NERLYNX to the body of the guidelines for the treatment of adjuvant HER2-positive Breast Cancer (BINV-L) under the heading Useful in Certain Circumstances, with a recommendation for considering extended adjuvant neratinib for patients with HR-positive, HER2-positive disease with a perceived high risk of recurrence.

The second update involved the inclusion of dose escalation as an approach to improve the tolerability of neratinib in the treatment of adjuvant HER2-positive Breast Cancer (BINV-L). This update aligns with the labeling supplement to the U.S. Prescribing Information approved by the U.S. Food and Drug Administration in June 2021, which incorporated the use of NERLYNX dose escalation as evaluated in the Phase II CONTROL study.

Joyce O'Shaughnessy, M.D., Baylor University Medical Center, Texas Oncology, US Oncology, Dallas Texas, said, "Oncologists should be aware of an important recent update to the NCCN guidelines that now include adjuvant neratinib to be used in certain circumstances, i.e., high-risk HR+, HER2+ early-stage breast cancer patients. These high-risk patients need access to every available treatment option proven to decrease their risk of recurrence, and the new NCCN guidelines update supports neratinib in this context."

Alan H. Auerbach, Chief Executive Officer and President of Puma, added, "The NCCN guidelines are utilized by many institutions, practices and clinicians who treat breast cancer patients. These updates help to increase the awareness of neratinib within the guidelines and should further support neratinib as an appropriate option to reduce the risk of recurrence for patients battling HER2-positive breast cancer."

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 the National Comprehensive Cancer Network

The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit alliance of leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating

quality, effective, efficient, and accessible cancer care so patients can live better lives. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) provide transparent, evidence-based, expert consensus recommendations for cancer treatment, prevention, and supportive services; they are the recognized standard for clinical direction and policy in cancer management and the most thorough and frequently updated clinical practice guidelines available in any area of medicine. The NCCN Guidelines for Patients® provide expert cancer treatment information to inform and empower patients and caregivers, through support from the NCCN Foundation®. NCCN also advances continuing education, global initiatives, policy, and research collaboration and publication in oncology. Visit NCCN.org for more 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. 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 Regarding NERLYNX® (neratinib) U.S. Indication

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: Manage diarrhea through either NERLYNX dose escalation or loperamide prophylaxis. If diarrhea occurs despite dose escalation or loperamide, treat with loperamide, 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. 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. Or separate NERLYNX by at least 3 hours with antacids.
- Strong CYP3A4 inhibitors: Avoid concomitant use.
- P-gp and moderate CYP3A4 dual inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- Certain P-gp substrates: Monitor for adverse reactions of P-gp substrates for which minimal concentration change may lead to serious adverse reactions 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