



News Release

Puma Biotechnology and Strata Oncology Announce Collaboration to Accelerate Enrollment in Neratinib HER2 Mutation Basket Study (SUMMIT Trial)

LOS ANGELES, Calif. and ANN ARBOR, Mich., July 17, 2018 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, and Strata Oncology, Inc., a precision oncology company, have entered into a collaborative agreement to accelerate patient enrollment in Puma’s ongoing Phase II SUMMIT trial of PB272 (neratinib). The SUMMIT trial is a global, multi-histology, open-label, precision-medicine ‘basket’ study evaluating the safety and efficacy of neratinib in patients with a wide variety of solid tumors with activating EGFR, HER2 or HER4 mutations.

Neratinib, an oral irreversible pan-HER kinase inhibitor, was approved by the 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[®]. Data published in the journal *Nature* earlier this year showed neratinib has activity across multiple tumor types with HER2-activating mutations.

Under the terms of the agreement, Strata will exclusively refer HER2-mutated advanced cancer patients identified through the Strata Trial for consideration of enrollment to Puma’s SUMMIT Trial for neratinib.

The Strata Trial is a screening protocol providing comprehensive tumor molecular profiling to advanced cancer patients at no cost and proactive enrollment support for a portfolio of pharmaceutical-sponsored precision therapy trials. Tumor profiling through the Strata Trial is provided as part of routine care to solid tumor patients across the Strata Precision Oncology Network, a network of 11 leading health systems representing more than 85,000 new cancer patients annually. This large network of trial-ready health systems with fully pre-screened advanced cancer populations enables rapid and predictable enrollment of precision therapy trials.

“We are pleased to partner with Puma Biotechnology to accelerate the path to new approvals for neratinib,” said Dan Rhodes, Ph.D., CEO of Strata Oncology. “We frequently identify HER2-mutant patients across the Strata Precision Oncology Network and we believe this partnership will greatly facilitate patient access to this promising clinical trial.”

“Puma’s ultimate goal is to deliver new treatment options and improve the lives of patients with various types of cancer,” said Alshad S. Lalani, V.P., Translational Medicine of Puma Biotechnology. “We believe Puma’s partnership with Strata will help us reach patients with multiple tumor types who may not otherwise know about the SUMMIT study, giving them a chance to participate in research that’s designed to provide important new information for future treatment.”

About Strata Oncology

Strata Oncology is a precision medicine company dedicated to transforming cancer care by systematizing precision oncology across a network of health systems and pharma companies. We empower health systems to deliver a cost-effective, system-wide precision oncology program, one that integrates cutting-edge molecular profiling and precision therapy trials with routine care, so that all advanced cancer patients have the opportunity to benefit. This large network of trial-ready health systems provides a mechanism to rapidly and predictably enroll precision therapy trials. For more information, visit www.strataoncology.com.

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 is a registered trademark of Puma Biotechnology, Inc.

Important Safety Information (ISI)

NERLYNX[®] (neratinib) tablets, for oral use

INDICATIONS AND USAGE: NERLYNX is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early-stage 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 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 ($\geq 5\%$) 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.

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.

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.

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 the expected benefits from the collaboration between Puma and Strata. All statements other than historical facts are forward-looking statements and are based on Puma's current expectations, forecasts and assumptions. 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 risk and uncertainties are identified in Puma's filings with the Securities and Exchange Commission, including its 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.

Contact

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500
info@pumabiotechnology.com
ir@pumabiotechnology.com

Strata Oncology Media Relations, +1 734 527 1000
media@strataoncology.com

David Schull or Amiad Finkelthal, Russo Partners, +1 212 845 4200
david.schull@russopartnersllc.com
amiad.finkelthal@russopartnersllc.com

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