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# Daiichi Sankyo and Puma Biotechnology Announce Research Collaboration with Major Cancer Center in HER2-Mutated Cancer

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## Terms:

## Dateline City:

TOKYO, BASKING RIDGE, N.J. & LOS ANGELES

TOKYO, BASKING RIDGE, N.J. & LOS ANGELES--(BUSINESS WIRE)--Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) and Puma Biotechnology, Inc. (Nasdaq: PBYI) have announced a preclinical research collaboration with Memorial Sloan Kettering Cancer Center (MSK) to explore the combination of Daiichi Sankyo's investigational antibody drug conjugate DS-8201 and Puma Biotechnology's irreversible pan-HER tyrosine kinase inhibitor neratinib (NERLYNX®) in HER2-mutated or HER2-positive solid tumors.

A team of scientists led by Maurizio Scaltriti, PhD, and in collaboration with a team of clinical investigators led by Bob Li, MD, will use isogenic models and established patient-derived xenograft models to assess the susceptibility of HER2-mutated or HER2-positive cancers to DS-8201, neratinib and other HER2-targeting therapies, elucidate mechanisms of action and resistance of these various tumor types, and evaluate the potential for synergistic combinations. Daiichi Sankyo and Puma Biotechnology will co-sponsor the research.

"Since early clinical data suggest that DS-8201 may have activity beyond breast and gastric cancers, the archetype HER2-driven tumors, we are interested in studying this asset on a molecular level as well as in combination with other HER2-targeting agents," said Tom Held, Vice President, Global Head, Antibody Drug Conjugate Task Force, Daiichi Sankyo. "In this collaboration, we are examining whether combining DS-8201 and neratinib, with its specific covalent binding to the HER2 receptor and associated increased internalization, is a rational combination therapy strategy to pursue. We are excited to join forces with Memorial Sloan Kettering and Puma to advance the understanding of combining HER2-targeted therapies to potentially treat various forms of HER2-mutated cancer."

"We are pleased to enter into this research collaboration with Memorial Sloan Kettering and Daiichi Sankyo to explore the combination of neratinib and DS-8201," said Alan Auerbach, Puma's Chief Executive Officer and President. "Combination therapy with agents that address different and complementary pathways, with neratinib targeting the HER2 kinase and DS-8201 providing an innovative targeted delivery of a potent cytotoxic, represents an intriguing approach to the treatment of HER2 mutated tumors and helps to maximize the potential for both agents in treating cancers with a HER2 mutation."

## About DS-8201

DS-8201 is the lead product in the ADC Franchise of the Daiichi Sankyo Cancer Enterprise. ADCs are targeted cancer medicines that deliver cytotoxic chemotherapy ("payload") to cancer cells via a linker attached to a monoclonal antibody that binds to a specific target expressed on cancer cells. Designed using Daiichi Sankyo's proprietary ADC technology, DS-8201 is a smart chemotherapy comprised of a humanized HER2 antibody attached to a novel topoisomerase I inhibitor payload by a tetrapeptide-based linker. It is designed to target and deliver chemotherapy inside cancer cells and reduce systemic exposure to the cytotoxic payload (or chemotherapy) compared to the way chemotherapy is commonly delivered.

DS-8201 is currently in phase 2 clinical development for HER2-positive unresectable and/or metastatic breast cancer resistant or refractory to T-DM1 ([DESTINY-Breast01](#)), phase 2 development for HER2-positive advanced gastric resistant or refractory to trastuzumab ([DESTINY-Gastric01](#)) and phase 1 development for other HER2-expressing advanced/unresectable or metastatic solid tumors.

DS-8201 has been granted Breakthrough Therapy designation for the treatment of patients with HER2-positive, locally advanced or metastatic breast cancer who have been treated with trastuzumab and pertuzumab and have disease progression after ado-trastuzumab emtansine (T-DM1), and Fast Track designation for the treatment of HER2-positive unresectable and/or metastatic breast cancer in patients who have progressed after prior treatment with HER2-targeted therapies including T-DM1 by the U.S. Food and Drug Administration (FDA). DS-8201 is an investigational agent that has not been approved for any indication in any country. Safety and efficacy have not been established.

## About NERLYNX® (neratinib)

Neratinib 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® (neratinib) tablets.

## 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  $\geq 2$  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](http://www.NERLYNX.com) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**DRUG INTERACTIONS:**

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors (PPI) and H<sub>2</sub>-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](http://www.NERLYNX.com) or 1-855-816-5421.

**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. NERLYNX<sup>®</sup> (neratinib) is approved for commercial use by prescription in the United States as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed as NERLYNX. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, Puma is primarily focused on the commercialization of NERLYNX and the continued development of its other advanced drug candidates directed at the treatment of HER2-positive breast cancer. Puma believes that NERLYNX has clinical application in the potential treatment of several other cancers that over-express or have a mutation in HER2. Further information about Puma Biotechnology can be found at [www.pumabiotechnology.com](http://www.pumabiotechnology.com)

**About Daiichi Sankyo Cancer Enterprise**

The vision of Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking in order to create meaningful treatments for patients with cancer. We are dedicated to transforming science into value for patients, and this sense of obligation informs everything we do. Anchored by our Antibody Drug Conjugate (ADC) and Acute Myeloid Leukemia (AML) Franchises, our cancer pipeline includes more than 20 small molecules, monoclonal antibodies and ADCs stemming from our powerful research engines: our two laboratories for biologic/immuno-oncology and small molecules in Japan, and Plexxikon Inc., our small molecule structure-guided R&D center in Berkeley, CA. Compounds in development include: quizartinib, an oral FLT3 inhibitor, for newly-diagnosed and relapsed or refractory AML with FLT3-ITD mutations; DS-8201, an ADC for HER2-expressing breast and gastric cancer, and other HER2-expressing solid tumors; and pexidartinib, an oral CSF-1R inhibitor, for tenosynovial giant cell tumor (TGCT), which is also being explored in a range of solid tumors in combination with the anti-PD1 immunotherapy pembrolizumab. For more information, please visit: [www.DSCancerEnterprise.com](http://www.DSCancerEnterprise.com).

**About Daiichi Sankyo**

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: [www.daiichisankyo.com](http://www.daiichisankyo.com). Daiichi Sankyo, Inc., headquartered in Basking Ridge, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit: [www.dsi.com](http://www.dsi.com).

### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding the benefits of a research collaboration with Memorial Sloan Kettering and Daiichi Sankyo, including whether a combination of neratinib and DS-8201 will be successful or beneficial, the benefits of NERLYNX® and neratinib, Puma's clinical trials and the announcement of data relative to those trials. All forward-looking statements included in this press release 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 fact that Puma has only recently commenced commercialization and shipment of its only FDA approved product; Puma's dependence upon the commercial success of NERLYNX (neratinib); Puma's history of operating losses and its expectation that it will continue to incur losses for the foreseeable future; risks and uncertainties related to Puma's ability to achieve or sustain profitability; Puma's ability to predict its future prospects and forecast its financial performance and growth; failure to obtain sufficient capital to fund Puma's operations; the effectiveness of sales and marketing efforts; Puma's ability to obtain FDA approval or other regulatory approvals in the United States or elsewhere for other indications for neratinib or other product candidates; the challenges associated with conducting and enrolling clinical trials; the risk that the results of clinical trials may not support Puma's drug candidate claims; even if approved, the risk that physicians and patients may not accept or use Puma's products; Puma's reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates; risks pertaining to securities class action, derivative and defamation lawsuits; Puma's dependence on licensed intellectual property; and the other 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

### **Language:**

English

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