News Release

Puma Biotechnology Announces Results of Phase II Trial of PB272 in Neoadjuvant Treatment of HER2-Positive Locally Advanced Breast Cancer

LOS ANGELES, **Calif., Dec. 10, 2015** – Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced that results from a randomized Phase II clinical trial of Puma's investigational drug PB272 (neratinib) in the neoadjuvant treatment of locally advanced HER2-positive breast cancer were presented at the 2015 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. The presentation entitled "NSABP FB-7: A Phase II Randomized Trial Evaluating Neoadjuvant Therapy Regimens with Weekly Paclitaxel plus Trastuzumab or Neratinib or Trastuzumab and Neratinib Followed by Doxorubicin and Cyclophosphamide with Postoperative Trastuzumab in Women with Locally Advanced HER2-Positive Breast Cancer" will be presented today at the poster discussion session. This trial was sponsored by the NSABP Foundation, Inc.

The FB-7 trial is a randomized Phase II clinical trial for women with HER2-positive locally advanced stage IIB-IIIC invasive breast cancer. Patients were randomly assigned to trastuzumab (T) or neratinib (N) or the combination (T+N) with weekly paclitaxel (P) followed by standard doxorubicin and cyclophosphamide chemotherapy (AC) administered prior to surgery. 126 U.S., Canadian, and European patients were randomly assigned to Arm 1 (T+P followed by AC), Arm 2 (N+P followed by AC) or Arm 3 (T+N+P followed by AC). The primary endpoint of the trial is pathological complete response rate (pCR) in the breast and lymph nodes.

Tumor tissue was collected on patients at the time of diagnosis. This tissue will be analyzed for several biomarkers including AKT, cMET, EGFR, ESR-alpha, HER2, HER3, HER4, p95 HER2 and PI3K and intrinsic subtypes. A key secondary endpoint of this trial is the molecular and genetic correlates of response for each of these biomarkers. The analysis of these biomarkers is ongoing and will be presented at a medical meeting in 2016.

For the intent-to-treat patient population (hormone receptor positive (HR+) and hormone receptor negative (HR-)), the pCR rate for Arm 1 was 38.1%, for Arm 2 was 33.3% and for Arm 3 was 50.0%. For the HR+ patients, the pCR rate for Arm 1 was 29.6%, for Arm 2 was 27.6% and for Arm 3 was 30.4%. For the HR- patients, the pCR rate for Arm 1 was 57.1%, for Arm 2 was 46.2% and for Arm 3 was 73.7%.

Pathological Complete Response Rate (pCR, breast and lymph nodes)			
Arm	**Arm 1 (T)**	**Arm 2 (N)**	**Arm 3 (N+T)**
Intent-to-Treat Population	38.1%	33.3%	50.0%
HR+ Patients	29.6%	27.6%	30.4%
HR- Patients	57.1%	46.2%	73.7%

The most frequently observed severe adverse event in the two neratinib treated arms of the trial (Arm 2 and Arm 3) was diarrhea. In the first 19 patients treated in Arm 2 of the trial, high dose loperamide (16 mg per day initially) as primary prophylaxis was not given to prevent the neratinib-related diarrhea. In this subset of patients the grade 3 diarrhea rate was 42% (8/19). In the next 10 patients treated in Arm 2 and the first 20 patients treated in Arm 3, high dose primary prophylaxis (16 mg per day initially) with loperamide was given during the initial two weeks of the first cycle of treatment. Using two weeks of intensive loperamide prophylactically, the grade 3 diarrhea rate in Arm 2 was 30% (3/10) and the grade 3 diarrhea rate in Arm 3 was 35% (7/20). In the next 13 patients in Arm 2 and 22 patients in Arm 3, high dose prophylaxis (16 mg per day initially) was given for the entire first cycle of treatment (4 weeks). The grade 3 diarrhea rate was 15% (2/13) in Arm 2 and 23% (5/22) in Arm 3.

Diarrhea	**No Prophylaxis**	**2-week Prophylaxis**		**4-week Prophylaxis**	
Arm	**Arm 2 (N) (n=19)**	**Arm 2 (N) (n=10)**	**Arm 3 (N+T) (n=20)**	**Arm 2 (N) (n=13)**	**Arm 3 (N+T) (n=22)**
Grade 3 Diarrhea (All Cycles)	8 (42%)	3 (30%)	7 (35%)	2 (15%)	5 (23%)

Dr. Samuel Jacobs, Emeritus Clinical Professor in the Department of Medicine, University of Pittsburgh School of Medicine, and the Director of Medical Affairs for the NSABP Foundation, Inc., said, "We are pleased to see the promising clinical activity of neratinib in combination with trastuzumab as measured by pCR rates in the hormone receptor negative patients. We look forward to completing the biomarker analysis to determine which patients may derive the greatest benefit from this dual anti-HER2 therapy."

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are pleased to complete this neoadjuvant trial of neratinib, both as a single agent and as a dual HER2 therapy in combination with trastuzumab. The results of the biomarker analysis should help us to determine the best path forward for neratinib in the neoadjuvant treatment of HER2 positive early stage breast cancer."

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. The Company aims to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. The Company is initially focused on the development of PB272 (oral neratinib), a potent irreversible tyrosine kinase inhibitor, for the treatment of patients with HER2-positive breast cancer and patients with non-small cell lung cancer, breast cancer and other solid tumors that have a HER2 mutation.

Further information about Puma Biotechnology can be found at www.pumabiotechnology.com.

Forward-Looking Statements:

This press release contains forward-looking statements, including, but not limited to, statements regarding the development of our drug candidates and the anticipated timing of various clinical trials and the announcement of data relative to these trials. All forward-looking statements included in this press release involve risks and uncertainties that could cause the Company'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 the Company has no product revenue and no products approved for marketing; the Company's

dependence on PB272, which is still under development and may never receive regulatory approval; the challenges associated with conducting and enrolling clinical trials; the risk that the results of clinical trials may not support the Company's drug candidate claims; even if approved, the risk that physicians and patients may not accept or use the Company's products; the Company's reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates; the Company's dependence on licensed intellectual property; and the other risk factors disclosed in the periodic reports filed by the Company with the Securities and Exchange Commission from time to time, including the Company's Annual Report on Form 10-K for the year ended December 31, 2014 and any subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to update these forward-looking statements, except as required by law.

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