



## News Release

### **Puma Biotechnology Announces Positive Top Line Results from Phase III PB272 Trial in Adjuvant Breast Cancer (ExteNET Trial)**

*Neratinib Achieves Statistically Significant Improvement in Disease Free Survival  
Company Plans to File for Regulatory Approval in First Half of 2015*

**LOS ANGELES, Calif., July 22, 2014** – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced top line results from the Phase III clinical trial of Puma's investigational drug PB272 (neratinib) for the extended adjuvant treatment of breast cancer (ExteNET Trial). The ExteNET trial is a double-blind, placebo-controlled, Phase III trial of neratinib versus placebo after adjuvant treatment with trastuzumab (Herceptin) in women with early stage HER2-positive breast cancer.

More specifically, the ExteNET trial enrolled 2,821 patients in 41 countries with early-stage HER2-positive breast cancer who had undergone surgery and adjuvant treatment with trastuzumab. After completion of adjuvant treatment with trastuzumab, patients were randomized to receive extended adjuvant treatment with either neratinib or placebo for a period of one year. Patients were then followed for recurrent disease, ductal carcinoma in situ (DCIS), or death for a period of two years after randomization in the trial.

The primary endpoint of the trial was disease free survival (DFS). The results of the trial demonstrated that treatment with neratinib resulted in a 33% improvement in disease free survival versus placebo. The hazard ratio was determined to be 0.67 which was statistically significant with a p-value of 0.0046. The secondary endpoint of the trial was disease free survival including ductal carcinoma in situ (DFS-DCIS). The results of the trial demonstrated that treatment with neratinib resulted in a 37% improvement in disease free survival including ductal carcinoma in situ versus placebo. The hazard ratio was determined to be 0.63 which was statistically significant with a p-value of 0.0009. Based on these results from the ExteNET study, Puma plans to file for regulatory approval of neratinib in the extended adjuvant setting in the first half of 2015.

Full results of the ExteNET trial for PB272 will be presented at a future scientific meeting

“We are very pleased with the results of the ExteNET trial with neratinib. This represents the first trial with a HER2 targeted agent that has shown a statistically significant benefit in the extended adjuvant setting, which we believe provides a meaningful point of differentiation for neratinib in the treatment of HER2 positive breast cancer,” said Alan H. Auerbach, Chief Executive Officer and President. “While the use of trastuzumab in the adjuvant setting has led to a reduction in disease recurrence in patients with early stage HER2-positive breast cancer, there remains an unmet clinical need for further improvement in outcome in order to attempt to further reduce this risk of recurrence. The results of the ExteNET study demonstrate that we may be able to provide this type of improvement with neratinib to further help the patients with this disease.”

#### **Conference Call and Webcast**

The Company will host a conference call to discuss the ExteNET trial results, as well as the amendment to the license agreement for neratinib, at 2:00 p.m. PDT (5:00 p.m. EDT) on Tuesday, July 22, 2014. The conference call may be accessed by dialing 1-877-709-8150 for domestic callers and 1-201-689-8354 for international callers. Please specify to the operator that you would like to join the “Puma Biotechnology Update Call.” The conference call will also be webcast live and accessible through the Investor Relations section of Puma’s website at [http://www.pumabiotechnology.com/ir\\_events.html](http://www.pumabiotechnology.com/ir_events.html) and will be archived there for 30 days following

the call. Please visit Puma's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

### **About Puma Biotechnology**

Puma Biotechnology, Inc. is a development stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. The Company focuses on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seeks to further develop those drug candidates for commercial use. 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](http://www.pumabiotechnology.com).

### **Forward-Looking Statements:**

This press release contains forward-looking statements, including statements regarding anticipated timing for the presentation of data relative to clinical trials and plans to file for regulatory approval. 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, 2013. 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.

### **Contacts:**

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

[info@pumabiotechnology.com](mailto:info@pumabiotechnology.com)

[ir@pumabiotechnology.com](mailto:ir@pumabiotechnology.com)

Andreas Marathovouniotis or David Schull, Russo Partners, +1 212 845 4235

[andreas.marathis@russopartnersllc.com](mailto:andreas.marathis@russopartnersllc.com)

[david.schull@russopartnersllc.com](mailto:david.schull@russopartnersllc.com)

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