News Release

Puma Biotechnology Announces Positive Top Line Results from PB272 Phase II Trial in HER2 Positive Metastatic Breast Cancer (NEfERTT Trial)

Neratinib Achieves Statistically Significant Reduction in Incidence of Central Nervous System Metastases

LOS ANGELES, **Calif., Nov. 13, 2014 –** Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced top line results from a Phase II clinical trial of Puma's investigational drug PB272 (neratinib) for the treatment of first-line HER2-positive locally recurrent or metastatic breast cancer (NEfERTT trial). The NEfERTT trial is a randomized, two-arm Phase II trial of neratinib plus the anticancer drug paclitaxel versus trastuzumab (Herceptin) plus paclitaxel as a first-line treatment for HER2-positive locally recurrent or metastatic breast cancer.

The NEfERTT trial enrolled 479 patients in 33 countries with locally recurrent or metastatic breast cancer who had not received prior anticancer therapy for locally recurrent or metastatic disease. Patients were randomized to receive first-line treatment with either paclitaxel plus neratinib or paclitaxel plus trastuzumab. The primary endpoint of the trial was progression free survival (PFS). The secondary endpoints of the study included objective response rate (ORR) and the incidence of central nervous system (CNS) metastases, including brain metastases.

The safety results of the study showed that the most frequently observed adverse event for the patients who received the combination of paclitaxel plus neratinib was diarrhea, with approximately 30% of the patients experiencing grade 3 diarrhea. The rate of grade 3 diarrhea in the patients who received the combination of paclitaxel plus trastuzumab was approximately 4%. Patients who received neratinib in this trial did not receive any prophylaxis with antidiarrheal agents to prevent the neratinib related diarrhea. Puma's recently reported clinical data from a Phase II trial of neratinib in HER2 mutated non-small cell lung cancer demonstrated that the use of high dose loperamide greatly reduces the rate of grade 3 diarrhea with neratinib. In that trial the grade 3 diarrhea rate was 8% in the patients who received neratinib monotherapy. In all of its current ongoing studies Puma is instituting the use of high dose loperamide in order to continue to reduce the neratinib related diarrhea.

The primary endpoint of the NEfERTT trial was progression free survival. The results of the trial demonstrated that the progression free survival for the patients who received the combination of paclitaxel plus neratinib was 16.6 months and the progression free survival for the patients who received the combination of paclitaxel plus trastuzumab was 16.7 months (p=0.35). The objective response rate in the trial for the patients who received the combination of paclitaxel plus neratinib was 74.8% and the objective response rate for the patients who received the combination of paclitaxel plus trastuzumab was 75.1% (p=0.94). These results did not demonstrate a statistically significant difference between the PFS and ORR results for the two treatment arms, which was consistent with expectations.

With respect to the incidence of central nervous system metastases (e.g., brain metastases), treatment with the combination of paclitaxel plus neratinib resulted in a 52.6% reduction in the incidence of CNS metastases compared to the incidence of CNS metastases in patients who received the combination of paclitaxel plus trastuzumab. The incidence of CNS metastases was 7.4% in the patients who received paclitaxel plus neratinib, while the incidence of CNS metastases in the patients who received the combination of paclitaxel plus trastuzumab was 15.6% (p=0.006). These results reflect a statistically significant difference between the two treatment arms.

Full results of the NEfERTT trial for PB272 will be presented at a future scientific meeting in 2015.

"We are very pleased with the results of the NEfERTT trial with neratinib," said Alan H. Auerbach, Chief

Executive Officer and President. “As expected, there was no statistically significant difference in progression free survival and objective response rate for the paclitaxel plus neratinib arm compared to the paclitaxel plus trastuzumab arm. However, the paclitaxel plus neratinib arm showed a statistically significant decrease in the incidence of CNS metastases compared to the paclitaxel plus trastuzumab arm. This represents the first randomized trial with a HER2 targeted agent that has shown a statistically significant reduction in the incidence of CNS metastases, which we believe provides a meaningful point of differentiation for neratinib in the treatment of HER2 positive breast cancer. While the development of other HER2 targeted drugs has produced a clinically meaningful benefit to patients with HER2 positive breast cancer, these drugs have had little impact on CNS metastases. As a result, we believe that there remains an unmet clinical need for reducing the incidence of CNS metastases and the results of the NEfERTT study demonstrate that we may be able to provide this type of improvement with neratinib.”

Conference Call and Webcast

The Company will host a conference call to discuss the NEfERTT trial results at 2:00 p.m. PST (5:00 p.m. EST) on Thursday, November 13, 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 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.

Forward-Looking Statements:

This press release contains forward-looking statements, including statements regarding anticipated timing for the presentation of data relative to clinical 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, 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.

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