



News Release

Puma Biotechnology Announces Positive PB272 (Neratinib) Phase II Data at CTRC-AACR San Antonio Breast Cancer Symposium

Phase II Results Demonstrate Efficacy of PB272 in Combination with Capecitabine and in Combination with Temozolomide in HER2+ Metastatic Breast Cancer

Los Angeles, Calif., Dec. 9, 2011—Puma Biotechnology, Inc., a development stage biopharmaceutical company, announced that results from ongoing Phase II clinical trials of Puma's investigational drug PB272 (neratinib) were presented at the 2011 CTRC-AACR San Antonio Breast Cancer Symposium that is currently taking place in San Antonio, Texas. These presentations are further detailed below:

Safety and Efficacy of Neratinib in Combination With Capecitabine in Patients With ErbB2-positive Breast Cancer

The Phase I/II clinical trial of PB272 given in combination with the chemotherapy drug capecitabine was conducted at numerous locations in the United States, Europe and Asia. The trial was sponsored by Pfizer and the Phase I results of this trial were previously presented last year. The Phase II portion of the study, presented at this symposium, enrolled patients with confirmed ErbB2+ (HER2+) metastatic or locally advanced breast cancer, and documented disease progression following prior treatment with trastuzumab and taxane chemotherapy. Patients were administered PB272 at a dose of 240 mg per day in combination with capecitabine given at a dose of 1,500 mg/m² (750 mg/m² twice daily) on Days 1 to 14 of each 21-day cycle.

The results of the study showed that the combination of PB272 and capecitabine had acceptable tolerability. The most frequently observed severe adverse event in the trial was diarrhea with 26% of the patients experiencing grade 3/4 diarrhea. The diarrhea was reported to be transient and managed with antidiarrheal agents and dose modifications. The efficacy results from the trial showed that for the 61 patients in the trial who had not been previously treated with the HER2 targeted agent lapatinib, 7 (11%) patients experienced a complete response, 32 (52%) patients experienced a partial response and 5 (8%) patients experienced stable disease for greater than 6 months, which translates to an overall response rate of 64% and a clinical benefit rate of 72%. In addition, for the 7 patients in the trial who had previously been treated with lapatinib, 1 (14%) patient experienced a complete response, 3 (43%) patients experienced a partial response and 1 (14%) patient experienced stable disease for greater than 6 months, which translates to an overall response rate of 57% and a clinical benefit rate of 71%. The median progression free survival (PFS) for patients who had not received prior treatment with lapatinib was 40.3 and the median PFS for the patients who had received prior lapatinib treatment was 35.9 weeks.

A Phase II, Randomized, Open-label Study of Neratinib Versus Lapatinib Plus Capecitabine for 2nd/3rd-line Treatment of HER2+ Locally Advanced or Metastatic Breast Cancer

The Phase II randomized trial of PB272 given as monotherapy versus the combination of lapatinib given in combination with capecitabine was conducted at numerous locations in the United States, Europe and Asia. The trial was sponsored by Pfizer. In the trial, patients who had confirmed HER2+ metastatic or locally advanced breast cancer and disease progression following prior treatment with trastuzumab and taxane chemotherapy were enrolled. Patients were randomized to receive either PB272 given as monotherapy daily at a dose of 240 mg per day or the combination of lapatinib given daily at a dose of 1,250 mg per day in combination with capecitabine given at a dose of 2,000 mg/m² (1,000 mg/m² twice daily) on Days 1 to 14 of each 21-day cycle.

The results of the study showed that the most frequently observed severe adverse events in the trial were diarrhea and palmar-plantar erythrodysesthesia (PPE, or hand-foot syndrome). More specifically, 28% of the patients in the neratinib arm of the trial and 10% of the patients in the lapatinib/capecitabine combination arm of the trial experienced grade 3/4 diarrhea. No patients in the neratinib arm of the trial and 14% of the patients in the lapatinib/capecitabine combination arm of the trial experienced grade 3/4 PPE. The diarrhea with neratinib was reported to be transient and manageable with antidiarrheal medications. The efficacy results from the trial showed that for the 117 patients in the neratinib monotherapy arm of the trial, 2% of the patients experienced a complete response, 27% of the patients experienced a partial response and 15% of the patients experienced stable disease for greater than 6 months, which translates to an overall response rate of 29% and a clinical benefit rate of 44%. For the 116 patients in the trial treated with the combination of lapatinib and capecitabine, 4% of the patients experienced a complete response, 36% of the patients experienced a partial response and 23% of the patients experienced stable disease for greater than 6 months, which translates to an overall response rate of 40% and a clinical benefit rate of 63%. The median progression free survival (PFS) for patients in the neratinib monotherapy arm was 4.5 months and the median PFS for the patients who had received the combination of lapatinib and capecitabine was 6.8 months.

Combined Inhibition of mTORC1 with Temsirolimus and HER2 with Neratinib: A Phase I/II Study in Patients with Metastatic HER2-Amplified or Triple-Negative Breast Cancer

The Phase I/II clinical trial of PB272 given in combination with the chemotherapy drug temsirolimus was conducted at Memorial Sloan-Kettering Cancer Center. The trial was sponsored by Pfizer and the Phase I results of this trial were previously presented last year. The Phase II portion of the study, presented at this symposium, enrolled patients with either HER2+ metastatic breast cancer and disease progression on trastuzumab or with triple negative breast cancer. Patients in the study received a median of 3 prior cytotoxic regimens (range 1-12 prior regimens). Patients in the HER2+ cohort of the trial received a median of 2 prior trastuzumab containing regimens (range 1-9 prior regimens). Patients were administered PB272 at a dose of 240 mg per day in combination with temsirolimus given at a dose of 8 mg weekly.

The results of the study presented showed that the combination of PB272 and temsirolimus had acceptable tolerability. The most frequently observed severe adverse events for the 20 patients evaluable for safety were grade 3 diarrhea (10% of patients), grade 3 hyperglycemia (5%), mucositis (5%), leukopenia (5%), and fatigue (5%). The efficacy results from the trial showed

that for the 15 patients with HER2+ disease, 9 (60%) patients experienced a partial response and 1 (7%) patient experienced stable disease for greater than 6 months, which translates to a clinical benefit rate of 67%. Patients who experienced a partial response to the combination of neratinib plus temsirolimus demonstrated a maximum change in the size of their target lesions of between 33% and 83%. None of the 5 patients with triple negative breast cancer demonstrated a partial response or stable disease for greater than 6 months.

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are pleased with the PB272 data that has been presented at the San Antonio Breast Cancer Symposium. The combination of PB272 given in combination with capecitabine shows strong evidence of antitumor activity in second and third line HER2+ metastatic patients, which we believe could position the drug well compared to other agents currently used to treat second and third line disease. In addition, the data on the combination of PB272 in combination with temsirolimus demonstrates intriguing antitumor activity in a heavily pretreated population. We look forward to continuing to study both of these combinations as we advance PB272 into further development in the HER2+ metastatic breast cancer population.

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 (neratinib), an oral potent irreversible tyrosine kinase inhibitor, for the treatment of patients with HER2 positive metastatic breast cancer.

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

Forward-Looking Statements:

This press release contains forward-looking statements that 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 that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. These risks include, among other things, that the Company has no product revenue and no products approved for marketing, the Company's dependence on its lead drug candidate, 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 and the Company's dependence on licensed intellectual property and various other risks set forth from time to time in the Company's filings with the Securities and Exchange Commission, including but not limited to the risks discussed in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 11, 2011 and in its other filings with the Securities and Exchange Commission. 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, Puma Biotechnology, Inc. +1 310 443 4150

info@pumabiotechnology.com

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

andreas.marathis@russopartnersllc.com

david.schull@russopartnersllc.com