News Release

Puma Biotechnology Announces Presentation of Positive PB272 Phase II Data from I-SPY 2 TRIAL

Neratinib Graduates from I-SPY 2 TRIAL

LOS ANGELES, Calif., April 7, 2014 – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, today announced the presentation of positive results from the Phase II clinical trial of Puma's investigational drug PB272 (neratinib) for the neoadjuvant treatment of breast cancer (I-SPY 2 TRIAL) in an oral presentation at the American Association for Cancer Research (AACR) Annual Meeting 2014 in San Diego, California. The presentation entitled "Neratinib plus Standard Neoadjuvant Therapy for High-Risk Breast Cancer: Efficacy Results from the I-SPY 2 TRIAL" was presented today at the session entitled "Clinical Trials Symposium: Biomarker Driven Clinical Trials."

The I-SPY 2 TRIAL (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2) is a randomized Phase II clinical trial for women with newly diagnosed Stage 2 or higher (tumor size at least 2.5 cm) breast cancer that addresses whether adding investigational drugs to standard chemotherapy in the neoadjuvant setting is better than standard chemotherapy. The primary endpoint is pathological complete response (pCR) in the breast and the lymph nodes at the time of surgery. The goal of the trial is to match investigational regimens with patient subsets on the basis of molecular characteristics (referred to as biomarker signatures) that benefit from the regimen. The trial enrolled patients who had a high risk of relapse using up-front tumor profiling (including tumor size, hormone receptor status (HR), HER2 status, and the MammaPrint 70-gene signature test).

The I-SPY 2 TRIAL involves an adaptive trial design based on Bayesian predictive probability that a regimen will be shown to be statistically superior to standard therapy in an equally randomized 300-patient confirmatory trial. Regimens that have a high Bayesian predictive probability of showing superiority in at least one of 10 predefined signatures graduate from the trial. Regimens are dropped for futility if they show a low predictive probability of showing superiority over standard therapy in all 10 signatures. A maximum total of 120 patients can be assigned to each experimental regimen. A regimen can graduate early and at any time after having 60 patients assigned to it.

The neratinib-containing regimen (neratinib plus paclitaxel followed by doxorubicin and cyclophosphamide) graduated from the I-SPY 2 TRIAL based on having a high probability of success in Phase III with a signature of HER2-positive/HR-negative. In this group, treatment with the neratinib-containing regimen resulted in an estimated pCR rate of 55.6% compared to the control arm (standard neoadjuvant chemotherapy: paclitaxel in combination with Herceptin (trastuzumab) followed by doxorubicin and cyclophosphamide) which had an estimated pCR rate of 32.6%. The Bayesian probability of superiority for the neratinib-containing regimen (compared to standard therapy) is 94.9%, which is analogous to a p-value of 0.051. In addition, the Bayesian predictive probability of showing statistical superiority in a 300-patient Phase III randomized trial of paclitaxel plus neratinib versus paclitaxel plus trastuzumab, both followed by doxorubicin/cyclophosphamide, is 79.1%.

There were 115 patients assigned to neratinib in the trial, including 65 patients who were HER2-positive. For the patients in the trial who were HER2-positive (including those who were either hormone receptor-positive or negative), treatment with the neratinib-containing regimen resulted in an estimated pCR rate of 39.4% compared to the control arm, which demonstrated an estimated pCR rate of 22.8%. The Bayesian probability of

superiority for the neratinib-containing regimen is 95.4%, which is analogous to a p-value of 0.046. In addition, the Bayesian predictive probability of showing statistical superiority in a 300-patient Phase III randomized trial of paclitaxel plus neratinib versus paclitaxel plus trastuzumab is 72.7%.

Patients in the I-SPY 2 TRIAL were screened using the MammaPrint 70-gene signature test. The median MammaPrint score from the patients in the previous I-SPY 1 TRIAL who fit the eligibility criteria for I-SPY2 was used as a predefined stratification factor for the I-SPY 2 TRIAL. Patients in I-SPY 2 were stratified as either MammaPrint High (below the median from I-SPY 1) or MammaPrint Ultra High (above the median from I-SPY 1). For the 41 neratinib treated patients in the trial who were MammaPrint Ultra High (80.5% of which were HER2 negative), treatment with the neratinib-containing regimen resulted in an estimated pCR rate of 47.5% compared to the control arm, which demonstrated an estimated pCR rate of 29.4%. The Bayesian probability of superiority for the neratinib-containing regimen is 93.3%, which is analogous to a p-value of 0.067. In addition, the Bayesian predictive probability of showing statistical superiority in a 300-patient Phase III randomized trial of paclitaxel plus neratinib versus paclitaxel, alone for HER2-negative patients or in combination with trastuzumab for the HER2-positive patients, is 71.8%.

The most frequently observed severe adverse event in the trial was diarrhea. In the neratinib treated arm of the trial 39% of the patients experienced grade 3/4 diarrhea while 4% of the patients in the control arm experienced grade 3/4 diarrhea. More specifically, in the first 23 patients in the trial, the rate of grade 3/4 diarrhea was 43%. The trial then instituted more aggressive investigator education and therapeutic intervention with antidiarrheal agents and in the next 52 patients the grade 3/4 diarrhea rate dropped to 33%. The trial then instituted the use of low doses of loperamide prophylactically, more specifically, 6 mg on day 1 and then 4 mg for the first two weeks of therapy. In the next 41 patients treated using this low dose prophylaxis the grade 3/4 diarrhea rate was 34%. In Puma's ongoing neratinib trials, the Company is utilizing a prophylactic protocol in which a high dose of loperamide, more specifically 16 mg on day 1, then 12 mg for the next two days, then 8 mg for the first two weeks, is given together with neratinib. The ongoing analysis has continued to demonstrate that this high dose loperamide prophylaxis significantly reduces the incidence of grade 3 diarrhea down to less than approximately 5%.

The I-SPY 2 TRIAL is a collaborative effort among academic investigators from approximately 20 major cancer research centers across the country, the U.S. Food and Drug Administration, Quantum Leap Healthcare Collaborative, and the Foundation for the National Institutes of Health (FNIH) Cancer Biomarkers Consortium. Major supporters include The Safeway Foundation and the Bill Bowes Foundation.

"We are very pleased with the activity of neratinib in the I-SPY 2 TRIAL and honored to have been involved with such an innovative trial. This represents the first clinical data on neratinib in the neoadjuvant treatment of breast cancer and suggests that the combination of paclitaxel plus neratinib has potent activity for the treatment of HER2-positive breast cancer and a subset of patients with HER2-negative breast cancer," said Alan H. Auerbach, Chief Executive Officer and President. "We look forward to advancing PB272 forward for the neoadjuvant treatment of breast cancer and look forward to involvement with the I-SPY 3 TRIAL this year."

I-SPY 2 Principal Investigators Dr. Laura Esserman, Director of the Carol Franc Buck Breast Care Center and Co-Leader of the Breast Oncology Program at the University of California, San Francisco Helen Diller Family Comprehensive Cancer Center, and Dr. Donald Berry, Professor of the Department of Biostatistics at the University of Texas MD Anderson Cancer Center, stated, "We are excited for the opportunity to confirm these promising results in I-SPY 3 in our quest to get better treatments to those women who stand to benefit most."

Conference Call and Webcast

The Company will host a conference call to discuss the positive results of the I-SPY 2 TRIAL at 2:00 p.m. PDT (5:00 p.m. EDT) on April 7, 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 I-SPY 2 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 metastatic 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 commencement and completion 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, 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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