Puma Biotechnology Presents 3-Year Disease Free Survival Data from Phase III Trial of PB272 in Extended Adjuvant Breast Cancer (ExteNET Trial) at the 2015 San Antonio Breast Cancer Symposium

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LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced the presentation of updated 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. The data was presented today in an oral presentation at the 2015 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. Previous safety and efficacy data from this trial were reported in June at the American Society of Clinical Oncology (ASCO) 2015 Annual Meeting in Chicago, Illinois.

The ExteNET trial randomized 2,840 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, or death for a period of two years after randomization in the trial. The primary endpoint of the trial was invasive disease free survival (DFS). The results of the trial demonstrated that treatment with neratinib resulted in a 33% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.67, p = 0.009). The 2-year DFS rate for the neratinib arm was 93.9% and the 2-year DFS rate for the placebo arm was 91.6%. These results were previously reported at the 2015 American Society of Clinical Oncology meeting in June.

The presentation at SABCS involved an exploratory sensitivity analysis of the 3-year disease free survival data to examine the durability of treatment effect beyond the 2-year data included in the primary analysis. This analysis was not a pre-planned analysis in the statistical analysis plan for the trial. For the primary endpoint of the trial, invasive disease free survival (DFS), the results of the trial demonstrated that treatment with neratinib resulted in a 26% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.74, two sided p = 0.023). The 3-year DFS rate for the neratinib arm was 92.0% and the 3-year DFS rate for the placebo arm was 89.9%.

The previously published analysis of previous adjuvant trials of Herceptin have demonstrated that patients are at the highest risk of disease progression closest to the completion of their treatment with adjuvant trastuzumab (Perez et al, Journal of Clinical Oncology, 2014). For the 2,297 patients in the ExteNET trial who were treated in ExteNET less than one year from the completion of their adjuvant treatment with trastuzumab, the results of the trial demonstrated that treatment with neratinib resulted in a 28% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.72, two sided p = 0.02). For this group of patients, the 3-year DFS rate for the neratinib arm was 91.5% and the 3-year DFS rate for the placebo arm was 88.9%.

As an inclusion criteria for the ExteNET trial, patients needed to have tumors that were HER2 positive using local assessment. In addition, as a pre-defined subgroup in the trial, patients had centralized HER2 testing performed on their tumor as well. To date, centralized HER2 testing has been performed on 2,041 (72%) of the patients in the ExteNET trial, and further central testing on available samples is currently ongoing. For the 1,709 patients whose tumors were HER2 positive by central confirmation, the results of the trial demonstrated that treatment with neratinib resulted in a 30% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.70, two sided p = 0.037). The 3-year DFS rate for the centrally confirmed patients in the neratinib arm was 91.8% and the 3-year DFS rate for the centrally confirmed patients in the placebo arm was 89.6%. For the 1,392 patients in the ExteNET trial with centrally confirmed HER2 positive disease who were treated in ExteNET less than one year from the completion of their adjuvant treatment with trastuzumab, the results of the trial demonstrated that treatment with neratinib resulted in a 37% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.63, two sided p = 0.009). For this group of patients, the 3-year DFS rate for the neratinib arm was 91.7% and the 3-year DFS rate for the placebo arm was 88.2%.

For the pre-defined subgroup of 1,631 patients with hormone receptor positive disease, the results of the trial demonstrated that treatment with neratinib resulted in a 43% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.57, two sided p = 0.003). The 3-year DFS rate for the neratinib arm was 93.6% and the 3-year DFS rate for the placebo arm was 89.3%. For the 1,334 hormone receptor positive patients in the ExteNET trial who were treated in ExteNET less than one year from the completion of their adjuvant treatment with trastuzumab, the results of the trial demonstrated that treatment with neratinib resulted in a 43% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.57, two sided p = 0.004). For this group of patients, the 3-year DFS rate for the

neratinib arm was 93.3% and the 3-year DFS rate for the placebo arm was 88.6%. For the 903 patients in the trial whose tumors were hormone receptor positive and HER2 positive by central confirmation, the results of the trial demonstrated that treatment with neratinib resulted in a 57% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.43, two sided $p < 0.001$). The 3-year DFS rate for the hormone receptor positive patients who also had HER2 centrally confirmed disease in the neratinib arm was 94.4% and the 3-year DFS rate for centrally confirmed patients in the placebo arm was 88.0%.

“While the use of adjuvant trastuzumab has led to a reduction in disease recurrence in patients with early stage HER2-positive breast cancer, there remains an unmet clinical need to further reduce this risk of recurrence,” said Professor Arlene Chan, medical oncologist at Mount Hospital and the Vice Chair of the Breast Cancer Research Centre WA. “This exploratory analysis shows that 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 and that the treatment effect of neratinib appears to be maintained over time.”

“We are very pleased with these 3-year DFS follow up results from the ExteNET trial with neratinib. We continue to be pleased with the activity of neratinib in this group of patients and more specifically with the centrally confirmed HER2 cohorts and the hormone receptor positive subgroup of patients,” said Alan H. Auerbach, Chief Executive Officer and President of Puma. “We look forward to proceeding with the regulatory filings for neratinib for the extended adjuvant treatment of breast cancer in the United States and Europe, currently anticipated in the first quarter and first half of 2016, respectively.”

Conference Call and Webcast

The Company will host a conference call to discuss its ExteNET trial data presented at the SABCS at 12:00 p.m. CST (10:00 a.m. PST, 1:00 p.m. EST) on Friday, December 11, 2015. 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 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 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 timing of regulatory filings. 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.

Language:

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Contact:

Puma Biotechnology, Inc.
Alan H. Auerbach or Mariann Ohanesian, +1 424-248-6500
info@pumabiotechnology.com
ir@pumabiotechnology.com
or
Russo Partners
Robert E. Flamm, Ph.D. or David Schull, +1 212-845-4226
robert.flamm@russopartnersllc.com
david.schull@russopartnersllc.com

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