News Release

Puma Biotechnology Presents Positive PB272 Clinical Data at ASCO 2012 Annual Meeting

Phase I Results Demonstrate Safety and Efficacy of PB272 in Combination with Paclitaxel and Trastuzumab in Women with Metastatic HER-2 Positive Breast Cancer

LOS ANGELES, Calif., June 2, 2012 – Puma Biotechnology, Inc. (OTCBB: PBYI), a development stage biopharmaceutical company, announced that results from an ongoing Phase I clinical trial of its lead drug candidate PB272 (neratinib) given in combination with the anticancer drugs paclitaxel and trastuzumab in patients with metastatic HER-2 positive breast cancer were presented in a poster presentation at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting. This trial was sponsored by the National Surgical Adjuvant Breast and Bowel Project (NSABP), a clinical trials cooperative group supported by the National Cancer Institute (NCI).

A phase I dose-escalating study evaluating weekly paclitaxel with neratinib and trastuzumab in women with metastatic HER-2 positive breast cancer, NSABP FB-8.

The goal of the Phase I clinical trial was to determine the maximum tolerated dose of PB272 that could be given in combination with paclitaxel and trastuzumab to patients with metastatic HER-2 positive breast cancer. The study enrolled patients with confirmed HER-2 positive metastatic or locally advanced breast cancer, and documented disease progression following prior treatment with trastuzumab and taxane chemotherapy. Patients were administered PB272 at doses of 120 mg, 160 mg, 200 mg or 240 mg per day, respectively, in combination with paclitaxel given intravenously at a dose of 80 mg/m^2 on days 1, 8, and 15 of every 28 day cycle until disease progression and trastuzumab administered intravenously weekly using a 4 mg/kg loading dose, then 2 mg/kg weekly until disease progression.

The results of the study showed that of the 120 mg PB272 dose group, 1 of 3 patients developed a dose limiting toxicity (DLT) consisting of grade 3 diarrhea. Three additional patients were enrolled and none experienced DLT. At PB272 dose levels of 160 mg and 200 mg, there were no DLTs. At the PB272 240 mg dose level, 2 of 3 patients had DLTs involving grade 3 diarrhea. The efficacy results from the trial showed that for the 15 evaluable patients, 8 patients showed clinical activity. This included 1 patient with a complete response (CR) as per the RECIST criteria; 1 patient with non-measurable metastatic disease (skin metastases) who demonstrated a complete resolution of disease; 4 patients with a partial response as per the RECIST criteria; and 2 patients with ongoing stable disease, of whom 1 has been ongoing for over 4 months and 1 has been ongoing for over 10 months.

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are pleased to present the results of this Phase I trial at the ASCO Annual Meeting and to see such a strong indication of efficacy for PB272. In trials of other anti-HER tyrosine kinase inhibitors given in combination with paclitaxel and trastuzumab, the dose of the tyrosine kinase inhibitor needed to be greatly reduced, by as much as 50%, from the dose typically given as a single agent due to tolerability issues.

"Based on the results of this trial it appears that we may be able to administer PB272, when it is given in combination with paclitaxel and trastuzumab, at doses very close to the dose typically used when PB272 is administered as a single agent. This could position the drug well against other anti-HER tyrosine kinase inhibitors in various settings, including the neoadjuvant setting. We look forward to continuing to study this combination as we continue to advance PB272 into further development in the HER-2 positive 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 (oral neratinib), a 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, 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 risk factors disclosed in the periodic reports filed by the Company with the Securities and Exchange Commission from time to time. 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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