



Published on *Puma Biotechnology Investor Center* (<https://investor.pumabiotechnology.com>) on 3/10/15 6:05 am PDT

Puma Biotechnology Initiates Phase II Trial of PB272 in Early Stage HER2-Positive Breast Cancer

Release Date:

Tuesday, March 10, 2015 6:05 am PDT

Terms:**Dateline City:**

LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced the initiation of a Phase II trial of Puma's investigational drug PB272 (neratinib) for the extended adjuvant treatment of breast cancer.

The 70 patient study will be an open label single arm Phase II trial of PB272 monotherapy administered to patients with HER2-positive early stage breast cancer who have previously received adjuvant treatment with trastuzumab. Patients will receive extended adjuvant treatment with neratinib for a period of one year. Patients will receive primary prophylaxis with high dose loperamide (16 mg per day initially) in order to attempt to reduce the neratinib-related diarrhea. The primary endpoint of the trial is reduction in the incidence and severity of diarrhea.

"We are pleased to initiate this Phase II trial," said Alan H. Auerbach, Chief Executive Officer and President. "Because the ExteNET Phase III trial was run prior to the implementation of loperamide prophylaxis in clinical trials of neratinib, in the ExteNET Phase III trial neratinib was administered without loperamide prophylaxis. The results from this Phase II study will give us a better understanding of the safety of neratinib in the extended adjuvant setting with concurrent high dose loperamide administered and, importantly, to what degree the grade 3 neratinib-related diarrhea can be reduced. We anticipate that initial results from this trial should be available by yearend 2015 and would enable us to include this data in our NDA filing for neratinib in the extended adjuvant setting, which is currently anticipated for the first quarter of 2016."

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 regulatory filings and 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, 2014. 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:

English

Contact:

Puma Biotechnology, Inc.
Alan H. Auerbach or Mariann Ohanesian, +1 424-248-6500

info@pumabiotechnology.com

ir@pumabiotechnology.com

or

Russo Partners

Robert Flamm, Ph.D., or David Schull, +1 212-845-4226

robert.flamm@russopartnersllc.com

david.schull@russopartnersllc.com

Ticker Slug:

Ticker: PBYI

Exchange: NYSE

ISIN:

US74587V1070

Source URL: <https://investor.pumabiotechnology.com/press-release/puma-biotechnology-initiates-phase-ii-trial-pb272-early-stage-her2-positive-breast-can>