



Published on *Puma Biotechnology Investor Center* (<https://investor.pumabiotechnology.com>) on 4/14/15 5:45 am PDT

# Puma Biotechnology Expands Cohort in Phase II Trial of PB272 in HER2 Mutation Positive Cancer Patients

## Release Date:

Tuesday, April 14, 2015 5:45 am PDT

## Terms:

## Dateline City:

LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, has expanded the second cohort from its Phase II clinical trial of its lead drug candidate PB272 (neratinib) as a single agent in patients with solid tumors who have an activating HER2 mutation (basket trial). The cohort that has been expanded is the cohort that includes patients with metastatic non-small cell lung cancer and whose tumors have a HER2 mutation.

The Phase II basket trial, which was initiated in October 2013, is an open-label, multicenter, multinational study to evaluate the safety and efficacy of PB272 administered daily to patients who have solid tumors with activating (driver) ERBB mutations, including epidermal growth factor receptor (EGFR), HER2 and HER3. The cohorts (baskets) included in the study are (1) bladder/urinary tract cancer; (2) breast cancer; (3) colorectal cancer; (4) endometrial cancer; (5) gastric/esophageal cancer; (6) ovarian cancer; (7) all other solid tumors with a HER2 mutation; (8) EGFR mutated and/or amplified primary brain cancer; and (9) solid tumors with a HER3 mutation. The non-small cell lung cancer (NSCLC) patients initially entered the study in the "other solid tumors with a HER2 mutation" basket and due to the preliminary activity seen in the trial the Company has expanded the basket, as per the protocol for the trial. The expanded HER2 mutant NSCLC basket will now enroll a total of 18 patients.

Last year at the European Society for Medical Oncology (ESMO) 2014 Congress, Puma presented initial data from the Phase II clinical trial of PB272 (neratinib) for the treatment of patients with NSCLC with somatic HER2 mutations. The efficacy results from the trial showed that for the 13 patients in the trial who received neratinib monotherapy, no patient experienced a partial response, 7 (54%) patients achieved stable disease and 4 (31%) patients achieved clinical benefit (defined as a partial response or stable disease for 12 or more weeks). In addition, the median progression free survival of the neratinib monotherapy arm was 2.9 months. In that study, the majority of the patients had the YVMA exon 20 mutation and there was less representation from other HER2 mutations. In the patients with NSCLC who have been treated in the basket study thus far, a much more diverse and a broader representation of HER2 mutations has been seen. The Company believes that although it is early and difficult to draw definitive conclusions, it appears that neratinib may be more selectively active in some HER2 mutated NSCLC tumors compared to others, which may account for the difference in activity being seen in the HER2 mutated NSCLC patients treated in the basket trial compared to those treated in the prior trial. The Company will continue to monitor this activity as the trial progresses.

"We are pleased to expand the second cohort in the basket trial. Although it is early, we are pleased with the initial activity that we are seeing in the patients with HER2 mutated non-small cell lung cancer in the trial," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "We look forward to continuing enrollment into this initially expanded cohort and we look forward to expanding additional cohorts from the basket trial, which we anticipate being able to do later this year."

## 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](http://www.pumabiotechnology.com).

## Forward-Looking Statements:

This press release contains forward-looking statements, including statements regarding anticipated timing for the expansion of additional cohorts from the basket trial. 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

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**Ticker Slug:**

*Ticker:* PBYI

*Exchange:* NYSE

*ISIN:*

US74587V1070

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**Source URL:** <https://investor.pumabiotechnology.com/press-release/puma-biotechnology-expands-cohort-phase-ii-trial-pb272-her2-mutation-positive-cancer-p>