



Published on Puma Biotechnology Investor Center (<https://investor.pumabiotechnology.com>) on 12/6/18 5:00 am PST

Puma Biotechnology Presents Results from the Hormone Receptor Positive Subgroup in Phase III ExteNET Trial of Neratinib for HER2-Amplified, Early Stage Breast Cancer at the 2018 San Antonio Breast Cancer Symposium

Release Date:

Thursday, December 6, 2018 5:00 am PST

Terms:

Dateline City:

LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced that results from the subgroup of patients with hormone receptor positive (HR-positive) breast cancer from the Company's Phase III ExteNET Trial of neratinib for early stage HER2-Amplified breast cancer are being presented at the 2018 San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. The presentation entitled, "Efficacy of neratinib in hormone receptor-positive patients who initiated treatment within 1 year of completing trastuzumab-based adjuvant therapy in HER2+ early stage breast cancer: subgroup analyses from the phase III ExteNET trial," is being presented at a poster session by Dr. Frankie Ann Holmes, Texas Oncology/US Oncology Research, Houston Texas on Thursday, December 6 from 7:00 - 9:00 a.m. CST. A copy of this poster is posted on Puma's website at www.pumabiotechnology.com.

In September 2018, the European Commission (EC) granted marketing authorisation for NERLYNX® (neratinib) for the extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab based therapy. This poster presentation highlights the data that was the basis for the EC approval.

ExteNET was a Phase III multicenter, randomized, double-blind, placebo-controlled trial of neratinib in adult patients (n=2,840) with early stage HER2-positive breast cancer following adjuvant trastuzumab treatment. Participants were randomized to receive either neratinib (n=1420) or placebo (n=1420) for one year.

In the subgroup of 1334 patients with hormone receptor positive disease and who were less than one year from the completion of prior adjuvant trastuzumab based therapy, the data, presented in the poster, demonstrated that after two years of follow-up, invasive disease-free survival (iDFS) was 95.3% in the patients treated with neratinib compared with 90.8% in those receiving placebo (hazard ratio = 0.49; 95% CI: (0.30, 0.78); p=0.002). The presentation also showed that after five years of follow-up, invasive disease-free survival (iDFS) was 90.8% in the patients treated with neratinib compared with 85.7% in those receiving placebo (hazard ratio = 0.58; 95% CI: (0.41, 0.82); p=0.002).

The poster highlighted that in this same subgroup, distant disease-free survival (DDFS) was 96.1% in the patients treated with neratinib compared with 92.9% in those receiving placebo (hazard ratio = 0.53, 95% CI: (0.31, 0.88); p=0.015) after two years of follow-up. After five years of follow-up, distant disease-free survival (DDFS) was 92.4% in the patients treated with neratinib compared with 87.7% in those receiving placebo (hazard ratio = 0.57; 95% CI: (0.39, 0.83); p=0.003).

Additionally, in this population, there were 295 patients who did not achieve a pathological complete response (pCR) after treatment with neoadjuvant therapy. This exploratory subgroup is similar to the patient population in the Phase III KATHERINE trial of Kadlecyl. The data presented demonstrated that in this subgroup, after two years of follow-up, invasive disease-free survival (iDFS) was 89.9% in the patients treated with neratinib compared with 85.2% in those receiving placebo (hazard ratio = 0.64; 95% CI: (0.30, 1.29)). Longer term follow up demonstrated that at five years, invasive disease-free survival (iDFS) was 85.0% in the patients treated with neratinib compared with 77.6% in those receiving placebo (hazard ratio = 0.60; 95% CI: (0.33, 1.07)).

The profile and frequency of treatment-emergent adverse events in this subgroup of patients with hormone receptor positive disease and who are less than one year from the completion of prior adjuvant trastuzumab was similar compared with the overall safety population. The most common grade 3 treatment-emergent adverse events in this subgroup were diarrhea (neratinib, 39% vs placebo, 1%), nausea (1% vs <1%), and fatigue (2% vs <1%); rates in the overall safety population were diarrhea (neratinib, 40% [included one grade 4 event] vs placebo, 2%), nausea (2% vs <1%), and fatigue (2% vs <1%).

"Reducing the risk of disease recurrence remains a need for patients, despite advances in the treatment of early stage HER2-positive breast cancer," said Professor Michael Gnant, Department of Surgery, Medical University of Vienna, Austria. "This analysis shows that we may be able to provide this type of improvement with neratinib to further reduce this risk of recurrence."

Puma Biotechnology CEO and President Alan H. Auerbach added, "We are encouraged by the data in this patient population

and we are committed to continuing to expand NERLYNX accessibility to patients worldwide. We expect NERLYNX to be commercially available in Europe in 2019, beginning with our launch in Germany during the first half of 2019 and followed by additional countries throughout Europe in the second half of 2019.”

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. Puma in-licenses the global development and commercialization rights to three drug candidates — PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets. NERLYNX was granted marketing authorization by the European Commission for the extended adjuvant treatment of hormone receptor-positive HER2-positive early stage breast cancer in September 2018. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

Further information about Puma Biotechnology may be found at www.pumabiotechnology.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the benefits of NERLYNX® and neratinib and the timing for commercial launch of NERLYNX® in Europe. All forward-looking statements involve risks and uncertainties that could cause Puma’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 reports filed by Puma with the Securities and Exchange Commission from time to time, including Puma’s Annual Report on Form 10-K for the year ended December 31, 2017. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Puma assumes no obligation to update these forward-looking statements, except as required by law.

Language:

English

Contact:

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500
info@pumabiotechnology.com
ir@pumabiotechnology.com

David Schull or Alex Fudukidis, Russo Partners, +1-212-845-4271
david.schull@russopartnersllc.com
alex.fudukidis@russopartnersllc.com

Ticker Slug:

Ticker: PBYI

Exchange: NASDAQ

ISIN:

US74587V1070

Source URL: <https://investor.pumabiotechnology.com/press-release/puma-biotechnology-presents-results-hormone-receptor-positive-subgroup-phase-iii-exten>