News Release

Puma Biotechnology Presents Interim Results of Phase II CONTROL Trial of PB272 in Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer at the 2017 AACR Annual Meeting

LOS ANGELES, Calif., April 4, 2017 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced that interim results from a Phase II clinical trial of Puma's investigational drug PB272 (neratinib) were presented at the 2017 American Association for Cancer Research Annual Meeting (AACR) that is currently taking place in Washington, D.C. The presentation entitled, "Effects of adding budesonide or colestipol to loperamide prophylaxis on neratinib-associated diarrhea in patients with HER2-positive early stage breast cancer: the CONTROL trial," was presented as a poster presentation.

The main adverse event that has been seen to date in clinical trials of neratinib is diarrhea and more specifically grade 3 diarrhea. In the Phase III ExteNET trial of neratinib as extended adjuvant treatment of HER2-positive early stage breast cancer that has previously been treated with adjuvant Herceptin, 95.4% of the patients experienced all grade diarrhea and 39.8% of the patients experienced grade 3 or higher diarrhea (there was one event of grade 4 diarrhea). The CONTROL trial is an international, open-label, Phase II study investigating the use of loperamide prophylaxis with or without other agents in the reduction of neratinib-associated diarrhea that has a primary endpoint of the incidence of grade 3 diarrhea.

In the CONTROL trial, patients with HER2-positive early stage breast cancer who had completed trastuzumab-based adjuvant therapy received neratinib daily for a period of one year. High dose loperamide prophylaxis was given for the first 2 cycles (56 days) of treatment. Initially, the loperamide dosing used was 16 mg on day 1, then 12 mg on days 2 and 3 and then 6-8 mg on days 4-56 (original dosing). The protocol was later amended to simplify the regimen such that patients took 12 mg on days 1-14 and 8 mg on days 15-56 (modified dosing). The CONTROL trial was also expanded to include two additional cohorts. One cohort received the combination of loperamide and budesonide and the other cohort received the combination of loperamide plus colestipol. Budesonide is a locally acting corticosteroid that the Company believes targets the inflammation identified in a preclinical model of neratinib-induced diarrhea and colestipol is a bile acid sequestrant that the Company believes targets the bile acid malabsorption also seen in preclinical models of neratinib-induced diarrhea

The interim analysis of the trial presented in the poster included a total of 137 patients who received neratinib plus loperamide prophylaxis (28 patients taking the original dosing and 109 patients taking the modified dosing), 64 patients who received neratinib plus loperamide prophylaxis for 2 cycles and budesonide for 1 cycle, and 26 patients who received neratinib plus loperamide prophylaxis for 1 cycle and colestipol for 1 cycle.

The results of the trial showed that the incidence of grade 3 diarrhea for the 137 patients who received the loperamide prophylaxis was 30.7%. For the 137 patients who received the loperamide prophylaxis, the median number of grade 3 diarrhea episodes per patient was 1 and the median cumulative duration of grade 3 diarrhea was 3 days. For the 137 patients who received loperamide prophylaxis, 20.4% discontinued neratinib due to diarrhea.

For the 64 patients who received the combination of loperamide plus budesonide, the results of the trial showed that the incidence of grade 3 diarrhea was 23.4%. The median number of grade 3 diarrhea episodes per patient was 1 and the median cumulative duration of grade 3 diarrhea was 2 days. For the 64 patients who received loperamide plus budesonide prophylaxis, 9.4% discontinued neratinib due to diarrhea.

For the 26 patients who received the combination of loperamide plus colestipol, the results of the trial showed that the incidence of grade 3 diarrhea was 11.5%. The median number of grade 3 diarrhea episodes per patient was 2 and the median cumulative duration of grade 3 diarrhea was 2 days. For the 26 patients who received loperamide plus colestipol prophylaxis, no patient (0%) discontinued neratinib due to diarrhea. Further information is provided in Table 1 below:

Table 1: Characteristics of Treatment-Emergent Diarrhea

Study	**CONTROL**			**ExteNET**
Antidiarrheal prophylaxis	**Loperamide (original + modified)**	**Budesonide + loperamide**	**Colestipol + loperamide**	**Loperamide prn**
N (at data cut-off)	137	64	26	1408
Diarrhea, %				
Any grade	77.4	79.7	57.7	95.4
Grade 1	24.1	26.6	30.8	22.9
Grade 2	22.6	29.7	15.4	32.5
Grade 3	30.7	23.4	11.5	39.8
Grade 4	0	0	0	0.1
Median cumulative duration of diarrhea, days				
Any grade	12.0	10.0	8.0	59.0
Grade ≥2	4.0	3.0	2.0	10.0
Grade ≥3[a]	3.0	2.0	2.0	5.0
Median episodes of diarrhea per patient, n				
Any grade	2.0	4.0	3.0	8.0
Grade ≥2	2.0	2.0	2.0	3.0
Grade ≥3[a]	1.0	1.0	2.0	2.0
Median duration of neratinib treatment, months				
Median	10.6	5.1	1.7	11.6
Tolerability related to neratinib diarrhea				
Neratinib dose hold due to diarrhea, %	14.6	14.1	7.7	33.9
Neratinib dose reductions due to diarrhea, %	7. 3	1.6	3.8	26.4
Neratinib discontinuations due to diarrhea, %	20.4	9.4	0	16.8
Hospitalization due to diarrhea, %	1. 5	0	0	1.4

No grade 4 events in the CONTROL study; one grade 4 event in the ExteNET study.

In the ExteNET trial, higher grade (grade 2 and grade 3) diarrhea occurred early and persisted throughout the duration of the 12-month treatment period. In the CONTROL trial, in the loperamide prophylaxis, loperamide plus budesonide prophylaxis and loperamide plus colestipol prophylaxis arms, the results showed that higher grade diarrhea (grades 2 and 3) occurred early but did not typically recur. This is shown in more detail in Figure 1: Treatment Emergent Diarrhea, which is attached to this news release. In addition, a full copy of the poster that was presented at AACR is available on the Puma Biotechnology website.

During the course of the CONTROL trial there has been an increase in the proportion of patients previously treated with pertuzumab (mainly in the neoadjuvant setting). For the 55 patients in the loperamide prophylaxis cohort who received prior pertuzumab, the grade 3 diarrhea rate was 38.2% (Table 2). For the 82 patients who did not receive prior pertuzumab, the grade 3 diarrhea rate was 25.6%. For the 39 patients in the budesonide cohort who received prior pertuzumab, the grade 3 diarrhea rate was 10.3%. For the 25 patients in the budesonide cohort who did not receive prior pertuzumab, the grade 3 diarrhea rate was 36.0%. This analysis suggests that prior pertuzumab exposure may have led to a higher rate of grade 3 diarrhea in the CONTROL trial that was not effectively managed by loperamide prophylaxis alone but was more effectively managed by loperamide plus budesonide.

Table 2: Incidence of Grade 3 Diarrhea in CONTROL by Prior Pertuzumab Treatment

	Loperamide Cohort		**Budesonide Cohort**	
	Yes (n = 55)	No (n = 82)	Yes (n = 39)	No (n = 25)
Grade 3 Diarrhea	38.2%	25.6%	10.3%	36.0%

Dr. Carlos H. Barcenas, Assistant Professor, Department of Breast Medical Oncology and Associate Medical Director, Breast Cancer Survivorship Clinic for the University of Texas MD Anderson Cancer Center, said, "We are pleased to see the reduction in incidence, severity and duration of neratinib-associated diarrhea when using the three antidiarrheal prophylaxis regimens tested so far in this study. When using either the loperamide prophylaxis, the loperamide plus budesonide prophylaxis or the loperamide plus colestipol prophylaxis, there appears to be a reduction in the incidence and severity of grade 3 diarrhea with neratinib. Importantly, the severe grade 2 and grade 3 diarrhea, when using the prophylaxis, appears to be acute, self-limiting and manageable. Although the study is still ongoing, we are encouraged that the addition of budesonide or colestipol appears to greatly improve the tolerability of neratinib as well. We look forward to completing the loperamide plus colestipol cohort."

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are pleased to see the reductions in the incidence of severe neratinib-related diarrhea in the CONTROL trial when using the loperamide, loperamide plus budesonide or loperamide plus colestipol regimens. The severe diarrhea appears to become more acute, whereby it does not typically recur after the first month. We are also very encouraged by the improvements in tolerability that have been seen to date in the budesonide and the colestipol cohorts. This is a marked improvement in tolerability over what was seen in the ExteNET trial and we look forward to continuing to monitor this in the loperamide plus colestipol cohort."

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. The Company in-licenses the global development and commercialization rights to three drug candidates—PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, the Company is primarily focused on the development of the oral version of neratinib, and its most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. The Company believes that neratinib has clinical application in the treatment of several other cancers as well, including non-small cell lung cancer and other tumor types that over-express or have a mutation in HER2. 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 the development of the Company's drug candidates. 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 and current 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, 2016. 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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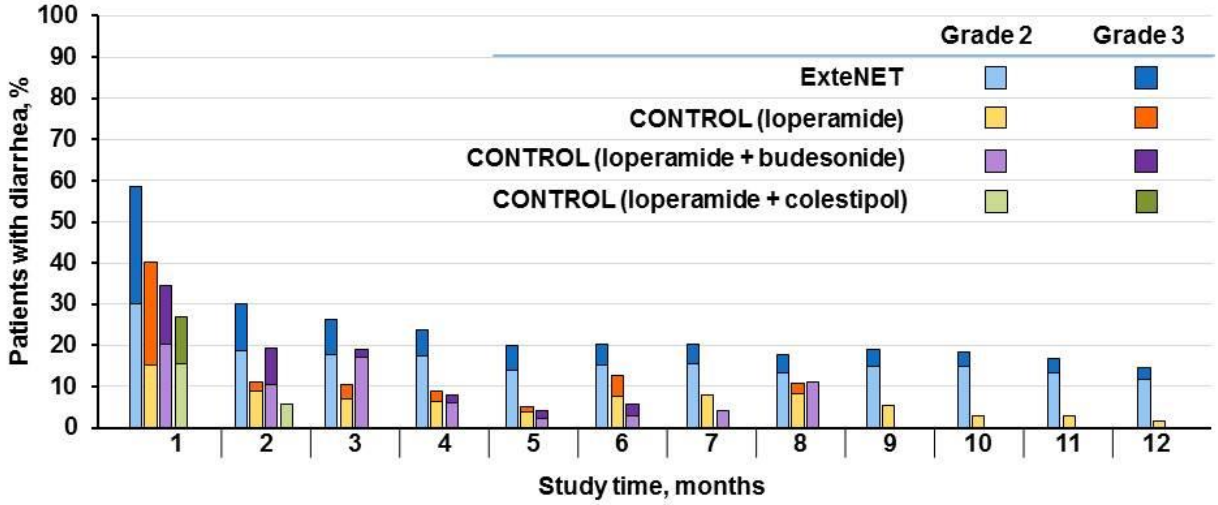
Figure 1
Treatment-Emergent Grade 2 and 3 Diarrhea by Months: CONTROL vs ExteNET



No. at risk

ExteNET	1408	1146	1074	1033	1006	971	935	924	911	888	873	863
CONTROL (lop)	137	90	85	79	78	78	79	74	74	72	72	67
CONTROL (bud)	64	57	53	51	48	35	25	18	9	6	2	0
CONTROL (col)	26	18	11	4	0	0	0	0	0	0	0	0

No Grade 4 events occurred in the CONTROL study