



Errata to the FDA Briefing Document
Oncologic Drugs Advisory Committee Meeting (ODAC)
May 24, 2017

Neratinib

Applicant: Puma Biotechnology, Inc.

**Errata to the FDA Briefing Document
ODAC Meeting**

Page 3, Table of Contents

Table 14: Overall Summary of Safety Analysis.....~~27~~ **Error! Bookmark not defined**

Page 3, Table of Contents

Figure 1: Kaplan-Meier Plot of Disease-free Survival; 2-year vs 1-year of trastuzumab (HERA)..... 6

Figure 24: Kaplan-Meier Plot of Disease-free Survival, ITT Population..... 17

Figure 32: Kaplan-Meier Plot of Disease-free Survival; 5-years of follow-up with 74.5% of patients reconsented..... 20

Page 10, Section 2.1

FDA denied a request by ~~Wyeth~~ **Wyatt** for a Special Protocol Assessment, as efficacy and safety had not been established in patients with metastatic breast cancer.

Page 11, Section 3.1

ER and/or PgR positive **vs.** ER and PgR negative

Page 13, Table 3

Table 3: Major Protocol Amendments and Changes to Statistical Analysis Plan

<p>October 14, 2011</p> <p>Amendment 9</p> <p>Sponsor: Pfizer</p>	<p>Due to changes in organizational strategy, recruitment stopped and follow up was shortened from 5-years to 2-years after randomization.¹</p> <p>Interim analyses were also removed.</p>	<p>Enrollment stopped at 2840 patients.</p> <p>The time-driven analysis precluded a pre-specified number of events but total sample size of the aITT population was expected to be 1700 with a total of 165 events. Assuming a hazard ratio of 0.67 and a one-sided significance level of 0.05, the power of the analysis was expected to be approximately 83%.</p>
<p>March 21 January 1, 2012</p> <p>Amendment 11</p>	<p>Pfizer transferred sponsorship of the IND to Puma</p>	

Page 14, Table 3 footnote:

The I-SPY 2 Study (neratinib HER2-negative arm graduation) was presented at **AACR ASCO** 2014.

Page 15, Table 4

Table 4: Patient Disposition

	Neratinib N=1420 n (%)	Placebo N=1420 n (%)
Patients who did not complete study*	300 (21)	215 (15) 237(17)

Page 16, Table 5

Table 5: Demographic and Baseline Characteristics

	Neratinib N=1420 n (%)	Placebo N=1420 n (%)
<i>HR status</i>		
Positive	816 (58)	815 818 (57)

Page 17

Figure 24: Kaplan-Meier Plot of Disease-free Survival, ITT Population

Page 21, Table 8

Table 8: Updated 2-year Analysis

	Neratinib (N=1420)	Placebo (N=1420)
Stratified Hazard Ratio	0.68 0.69 (0.51, 0.91)	

Page 30, Table 16

Table 16: Nonfatal Serious Adverse Reactions Reported in ≥ 5 Neratinib-Treated Patients on Study 3004

	Neratinib N=1420 n (%)	Placebo N=1420 n (%)
Cellulitis	6 (0.4)	4 (0.3) 1(0.1)