

# REDACTED

## VERDICT FORM

**FILED**

FEB 4, 2019

CENTRAL DISTRICT OF CALIFORNIA  
SOUTHERN DIVISION AT SANTA ANA

BY MKU

Deputy Clerk, U.S. District Court

**1. MISREPRESENTATIONS AND OMISSIONS**  
(Please refer to the statements in the attached Appendix.)

Did Plaintiffs prove that Defendants made materially false or misleading statements or omissions on July 22, 2014 regarding:

	<i>(circle either "yes" or "no" for each statement)</i>	
1. Disease-Free Survival (DFS) Rates	<input checked="" type="radio"/> YES	<input type="radio"/> NO
2. Grade 3+ Diarrhea Rate	<input type="radio"/> YES	<input checked="" type="radio"/> NO
3. Kaplan-Meier (KM) Curves	<input type="radio"/> YES	<input checked="" type="radio"/> NO
4. Discontinuation Rate Due to Adverse Events (AEs)	<input type="radio"/> YES	<input checked="" type="radio"/> NO

IF YOU CIRCLED "YES" AT LEAST ONCE, PROCEED TO SECTION 2.  
OTHERWISE, PROCEED TO SECTION 6.

**2. KNOWINGLY**

Did Plaintiffs prove that Defendants acted knowingly in making the alleged false or misleading statements or omissions? *(circle either "yes" or "no")*

YES       NO

IF YOU CIRCLED "YES," PROCEED TO SECTION 3.  
OTHERWISE, PROCEED TO SECTION 6.

**3. CAUSATION**

**3.1** Did Plaintiffs prove that the disclosures on May 13, 2015 regarding the ExteNET trial DFS Rates and Grade 3+ Diarrhea Rate played a substantial part in causing the decline in Puma's stock price on May 14, 2015? *(circle either "yes" or "no")*

YES       NO

PROCEED TO QUESTION 3.2.

SACV 15-00865-AG  
(SHKx)  
HSINGCHING HSU, ET AL. V.  
PUMA BIOTECHNOLOGY INC,  
ET AL

3.2 Did Plaintiffs prove that the disclosures on June 1, 2015 regarding the ExteNET trial KM Curves and Discontinuation Rate Due to Adverse Events played a substantial part in causing the decline in Puma's stock price on June 1-2, 2015? (circle either "yes" or "no")

YES

NO

IF YOU CIRCLED "YES" IN RESPONSE TO QUESTION 3.1 AND/OR QUESTION 3.2, PROCEED TO SECTION 4. OTHERWISE, PROCEED TO SECTION 6.

**4. DAMAGES**

Specify the amount of damages per share of Puma stock, if any, caused by the disclosures regarding the alleged false or misleading statements or omissions. (For each date for which you answered "yes" in response to Questions 3.1 and 3.2, write in a dollar amount.)

Date	(\$/share)
May 14, 2015	\$ <u>4.50</u> (The damages per share cannot exceed \$40.96)
June 1-2, 2015	\$ _____ (The damages per share cannot exceed \$46.24)

PROCEED TO SECTION 5.

**5. REBUTTING THE PRESUMPTION OF RELIANCE**

5.1 Did Defendants prove that Plaintiff Norfolk Pension Fund did not actually rely on the integrity of the market price of Puma's stock because it would have bought Puma stock at the same price it did, even if it had known of the alleged fraud? (circle either "yes" or "no")

YES

NO

PROCEED TO QUESTION 5.2.

5.2 Did Defendants prove that the alleged false or misleading statements or omissions on July 22, 2014 did not affect the market price of Puma's stock? (circle either "yes" or "no")

YES

NO

PROCEED TO SECTION 6.

6. RETURN OF VERDICT

SIGNED this 4 day of FEBRUARY, 2019.

PRESIDING JUROR:

 \_\_\_\_\_

**APPENDIX OF ALLEGED FALSE AND MISLEADING STATEMENTS  
AND SURROUNDING TEXT**

*(see Exhibit 103 for full transcript of the July 22, 2014 conference call)*

No.	Subject	July 22, 2014 Statements
1.	<b>Disease-Free Survival (DFS) Rates</b>	<p>WERBER: Congrats on this fantastically and, in many ways, unexpected data. So I have a ton of questions. Maybe I'll just take two, if you don't mind. One is, give us a little bit of a sense, what was the DFS on the control arm, first. And then second, help us understand, what do you know about the safety profile?</p> <p>AUERBACH: Okay. <i>So in terms of the DFS of the placebo arm of the trial, it was in line with other reported trials. So it's in line with the Herceptin adjuvant studies.</i> And then in terms of the safety profile, we haven't yet fully validated the safety database. Our anticipation is the main AE we're going to see is what we've historically seen with neratinib, which is the diarrhea. And again, we would anticipate that the diarrhea rate, the grade 3 diarrhea rate, would be in line with the 29% to 30% that's been seen in the prior studies of neratinib as a monotherapy.</p> <p align="center">* * *</p> <p>WERBER: <i>You're thinking that, if I'm correct, the DFS is probably around mid to high 80s, around 86% or so in the control arm?</i></p> <p>AUERBACH: <i>I would be comfortable with that number.</i></p> <p>WERBER: <i>And one would imagine you probably had to show around 90% or 91%? Is that reasonable?</i></p> <p>AUERBACH: <i>Yes. I think you can do a 33% improvement in DFS and come up with that calculation, given the numbers we gave.</i></p>

<p>2.</p>	<p><b>Grade 3+ Diarrhea Rate</b></p>	<p>AUERBACH (opening remarks): <i>From a safety perspective, the Company has not yet seen the safety results from the ExteNET trial for neratinib, as the data is still being validated.</i> Historically, the main adverse event that has been seen with neratinib has been a gastrointestinal adverse event, and more specifically, diarrhea. In previous studies performed prior to Puma licensing neratinib, grade 3 or higher diarrhea was seen in approximately 30% or more of the patients treated with neratinib. In these previous historical studies, the diarrhea was typically a first-cycle effect and was treated using a combination of anti-diarrheal agents, such as Imodium, which is also known generically as loperamide, dose interruptions, or dose reductions.</p> <p style="text-align: center;">* * *</p> <p>Prior to Puma licensing the drug, neratinib monotherapy was previously tested in two Phase II trials in patients with HER2-positive metastatic breast cancer, the results of which were published in European Journal of Cancer in December 2013 and the Journal of Clinical Oncology in 2010. <i>In those studies, grade 3 or higher diarrhea was seen in 29% and 30% of the patients, respectively.</i></p> <p>The ExteNET trial was started in April of 2009, prior to Puma licensing the drug in 2011. Neratinib was given as a monotherapy, and no prophylaxis to prevent neratinib-related diarrhea was used. <i>Therefore, the Company anticipates that the grade 3 diarrhea rates in the ExteNET trial are likely to be in line with what was previously published in the prior Phase II trials that were published in the European Journal of Cancer and the Journal of Clinical Oncology.</i></p> <p>As investors know, after licensing the drug, Puma began to look at using antidiarrheal agents, and specifically Imodium, prophylactically in order to reduce and potentially prevent the neratinib-related diarrhea. More specifically, the results of using both low doses and high doses of Imodium prophylactically have shown that using high doses of Imodium during the first 3 days of treatment and then tapering the Imodium dose down during the first cycle has resulted in much lower rates of grade 3 diarrhea.</p>
-----------	--------------------------------------	---

In all of its current ongoing studies. Puma is instituting the use of this high-dose Imodium in order to reduce the neratinib-related diarrhea. The results of this continues to demonstrate that the use of high-dose Imodium prophylaxis drops the grade 3 diarrhea rates considerably. We expect that the first clinical trial data utilizing this high-dose Imodium prophylaxis will be presented in the second half of 2014, and we believe that this will give investors much greater transparency into the success of this prophylaxis in reducing the grade 3 diarrhea with neratinib.

\* \* \*

WERBER: Congrats on this fantastically and, in many ways, unexpected data. So I have a ton of questions. Maybe I'll just take two, if you don't mind. One is, give us a little bit of a sense, what was the DFS on the control arm, first. And then second, help us understand, what do you know about the safety profile?

AUERBACH: Okay. So in terms of the DFS of the placebo arm of the trial, it was in line with other reported trials. So it's in line with the Herceptin adjuvant studies. And then in terms of the safety profile, we haven't yet fully validated the safety database. Our anticipation is the main AE we're going to see is what we've historically seen with neratinib, which is the diarrhea. *And again, we would anticipate that the diarrhea rate, the grade 3 diarrhea rate, would be in line with the 29% to 30% that's been seen in the prior studies of neratinib as a monotherapy.*

Now, again, they didn't use any prophylaxis. There was no Imodium prophylaxis used in the trial, because it was started before we had come up with that. In the current trial that we're doing, neratinib monotherapy, we've been very, very successful in being able to reduce the grade 3 diarrhea rates using the Imodium prophylaxis.



3.	<b>Kaplan-Meier (KM) Curves</b>	<p>LIANG: Congratulations, Alan, and your team. So can you – <i>I assume you have seen the curves for the two arms</i>. Can you give us a sense as to whether the separation is widening over time? Or how would you describe the curve separation?</p> <p>AUERBACH: <i>Yes, thanks for that question, Howard. Okay, so the trial started in April of 2009, and this data cut is as of October 2013. So that's essentially the last patient was followed for 2 years. So from those numbers, you can see we have a lot of patients who have been in for much more than that 2-year cutoff. If we look at the [Kaplan-Meier] curves going out beyond that, it looks like the curves are continuing to separate.</i></p> <p><i>And to give a little more detail on that, if you look at the curves in the Herceptin adjuvant trials – so the HERA study, the BCIRG study, et cetera – the absolute difference in disease-free survival increases as you go out year over year. So, for instance, in the BCIRG trial, the DFS difference was 6% at 2 years and 7% at 3 years, then 8% at 4 years, et cetera, et cetera . . .</i></p> <p><i>We're seeing the same preliminary trend in the ExteNET trial, where the curves appear to be continuing to separate as you go out year over year, and the absolute DFS difference is increasing year over year as well.</i></p>
----	---------------------------------	--

4.	<b>Discontinuation Rate Due to Adverse Events (AEs)</b>	<p>SCHMIDT: Thanks. And lastly, I think you probably do know the dropout rate from the trial. Could you remind us of that?</p> <p>AUERBACH: Dropout rate due to side effects?</p> <p>SCHMIDT: Sure, or anything, if you have it.</p> <p>AUERBACH: <i>I don't have that. I apologize. That's part of the stuff being validated, but we anticipate, typically in the neratinib studies – the legacy ones that were done before, when Pfizer was running it without any prophylaxis – it was usually in the 5% to 10% range was the dropout rate due to AEs. So we'd anticipate it's in that same vein.</i></p> <p style="text-align: center;">* * *</p> <p>RODEN: I just wanted to clarify an earlier answer to a question. So you were asked about the dropout rate, and I think you wanted to defer to dropouts due to – discontinuations due to adverse events. But can you just mention, or maybe I missed it, how many patients actually completed the year of therapy? Or another way of saying it is how much missing data is there from the DFS analysis?</p> <p>AUERBACH: <i>Yes, so in terms of patients who dropped out due to AEs, like I said, historically with neratinib, that should be somewhere in the 5% to 10% range.</i></p> <p>RODEN: Okay, but do you have a sense for dropouts for any reason across the study?</p> <p>AUERBACH: <i>No</i>, the main one we would expect is due to AEs. And obviously, if they progressed or died.</p>
----	---	--