



ERRATA

For

Cardiovascular and Renal Advisory Committee

Meeting

For Effient (prasugrel)

February 3, 2009

Silver Spring, MD

The following are errata for the FDA briefing material:

DIVISION OF CARDIOVASCULAR and RENAL PRODUCTS
Revised Secondary CDTL Review (Ellis F. Unger, M.D.)

1. Page 41 of 77, Under Concomitant Therapies: Stents: “no stent (0.82)” should read: “no stent (**0.67**).”
2. Page 50 of 77: last paragraph, line 4, “<60 kg” should read “ \leq 60 kg.”
3. Page 51 of 77, Table 12, next to last line: “weight <60 kg” should read “weight \leq 60 kg.”
4. Page 51 of 77, Table 12, footnote: “Weight <60 kg is a subset of quintile #1” should read “Weight \leq 60 kg is a subset of quintile #1.”
5. Page 76 of 77, next to last line: “The sponsor has initiated Study TABY, a ~13,000 subject study...” should read: “The sponsor has initiated Study TABY, a ~**10,300** subject study...”.

Clinical Review (Karen A. Hicks, M.D.)

1. Table 6, Page 7 of 146
No Prior History of TIA/CVA states “N=5831” and should read “**N=4831**.”
2. Table 51, Page 99
STEMI – Age < 65 – N% was “6.16” and should read “**8.16**.”
3. Table 51, Page 99 of 146

UA/NSTEMI – Age \geq 70 Female Clopidogrel “N = 17” and should read “N=**517**.”

4. Table 51, Page 99 of 146
ACS – Age \geq 70 Male Clopidogrel “N% = 9.70” and should be “N% = **15.91**.”
5. Table 51, Page 103 of 146
STEMI – GPIIb/IIIa inhibitors up to Cath Lab – HR 95% CI was “0.36, 0.34” and should be “**0.36, 1.34**.”
6. Table 28, Page 39 of 146
Prior TIA/CVA: The Yes and No rows have been reversed and should be “No” in Row 1 and “Yes” in Row 2.

OFFICE OF CLINICAL PHARMACOLOGY

This is an untitled review that begins with: “1. Executive Summary.” There are no page numbers. Assuming that the initial page is page 1:

1. Page 1: Change: “1.2 PHASE IV COMMINMENTS:” to “1.2 PHASE IV COMMITMENTS:”
2. Page 5: Under Biopharmaceutics, paragraph 2, change “78, 50, and 5%” to “78, **58**, and 5%.”
3. Page 31, under: “In vivo studies with medications that are likely to be administered for the treatment of ACS,” change:

“At 4 and 6 hours post-dose BTR increased by 36% in the warfarin/prasugrel (compared to the prasugrel arm).”

To:

“At **48** hours post-dose, BTR increased by 36% in the warfarin/prasugrel (compared to the prasugrel arm).”

DIVISION OF CARDIOVASCULAR AND RENAL PRODUCTS

Secondary Review of Cancer Adverse Events and Risk/Benefit (Thomas A. Marciniak, M.D.)

1. Page 29 of 41 of the Secondary Review, end of the middle paragraph:

The following text is incorrect and should be removed:

“The first two PPMIs I checked (010003 10565 and 10966) had CEC Adjudication: Cardiac Ischemic Events forms with the type of event sections filled out but the Section

A: Adjudication of Myocardial Infarction section not filled out and no signatures by CEC reviewers.”