

**ERRATA
to the
FDA Briefing Package**

**Oncologic Drugs Advisory Committee
March 13, 2008**

Page 4, paragraph 4, sentence 4 :

“In two randomized (1:1), multicenter studies limited to patients with SCLC, Studies N93-004, 980297, and 2001-0145 enrolling 224, 314, and 596 patients respectively; there was no evidence of worsened survival or poorer tumor outcome among those who also received an ESA.”

Corrected to read:

“In **three** randomized (1:1), multicenter studies in analyses limited to patients with SCLC, Studies N93-004, 980297, and 2001-0145 enrolling 224, **92**, and 596 SCLC patients respectively, there was no evidence of worsened survival or poorer tumor outcome among those who also received an ESA.”

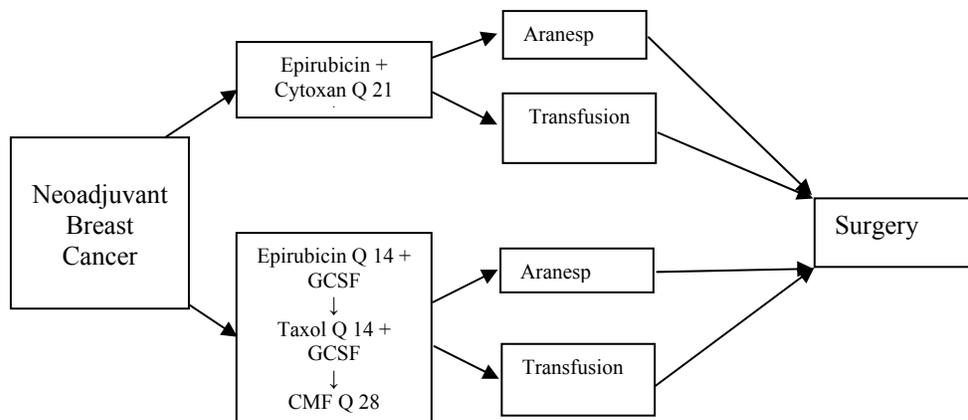
Page 11:

“Warnings updated to include adverse results from EPO-CAN-20 and 2000-0161 studies; studies also summarized in tabular format.”

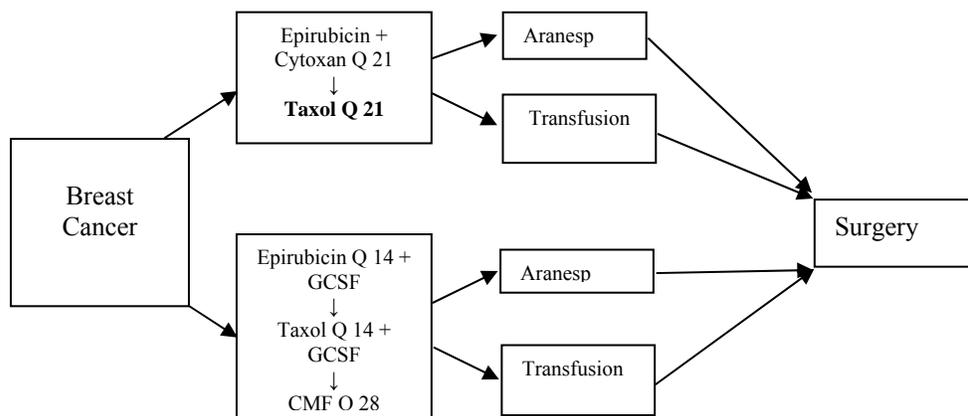
Corrected to read:

“Warnings updated to include adverse results from 2000-0161 study; studies also summarized in tabular format. “

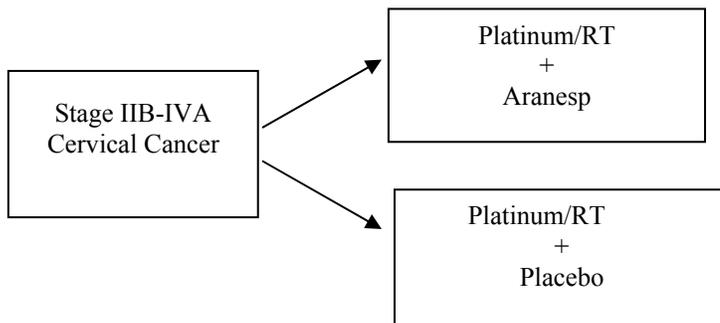
Page 12, Figure under “Summary of the PREPARE study”:



Because patients in every 21 day group received Taxol in addition to Epirubicin and Cytoxan, this figure has been corrected to read:



Page 15, Figure under “Summary of the GOG-191 study”:



Because epoetin alfa was used in the study, the figure has been corrected to read:

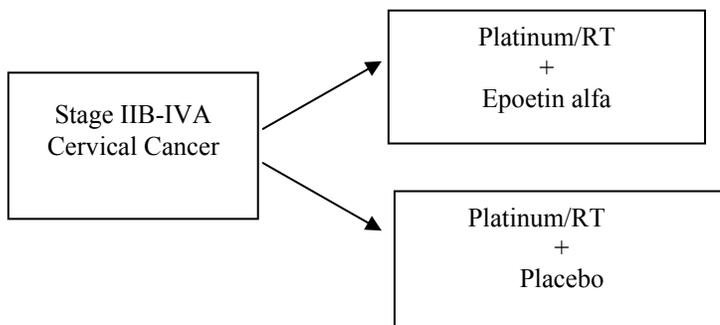


Table 4, third column, fifth row, under the BRAVE study.

“PFS: HR 1.09 (95% CI 0.90, 1.31, 0.393)”

Corrected to read:

“PFS: HR 1.09 (95% CI 0.90, 1.31, **p=0.393**)”

Table 4:

“† denotes studies prematurely terminated by Data Monitoring Committees or Data Safety Monitoring Boards”

Corrected to read:

“† denotes studies prematurely terminated by Data Monitoring Committees or Data Safety Monitoring Boards **or Sponsor**”

Appendix 2, page 36, first paragraph, section 1.2 :

“Tumor promotion and decreased survival were observed in several clinical studies most of which used unapproved dosing regimens”

Corrected to read:

“Tumor promotion and/or decreased survival were observed in several clinical studies, **all of which used unapproved dosing regimens or were in unapproved indications.**”

Appendix 2, page 36, third paragraph, section 1.2 :

“At the March 2007 ODAC ...”

Corrected to read

“At the **May** 2007 ODAC ...”

Appendix 2, page 37, first paragraph, section 2.1.1:

“Since the March 2007 ODAC ...”

Corrected to read

“Since the **May** 2007 ODAC ...”