Errata for the FDA Briefing Document fo Atrasentan for the September 13, 2005 ODAC Meeting
NDA 21-491

The following changes should be made to the FDA briefing document for Atrasentan

1. Page 35: The following sentences should be removed from the text box:

"A study synopsis was submitted to the FDA for an EOP2 meeting. No protocol or details were submitted. The trial endpoint is composite and unusual. The FDA had accepted the general idea of a composite endpoint in the EOP2 meetings."

2. Page 55: The following paragraph should be removed from page 55:

"Fifty-two (18%) patients were lost to follow-up. For 10 (3%) patients alive and not "lost to follow-up", no updated info was given for 6 – 15 months before the cut-off date. Because survival was to be updated up to every 3 months, these 3 % patients could be counted as "lost-to-follow-up" for the survival analysis, bring up the "lost-to-follow-up" percentage to 21%. The FDA analysis which follows the applicant's analysis censored 18% of patients."

The above paragraph should be replaced with:

"Fifty-two (6.5%) patients were lost to follow-up. For 10 (3%) patients alive and not "lost to follow-up", no updated info was given for 6 – 15 months before the cut-off date. Because survival was to be updated up to every 3 months, these 3 % patients could be counted as "lost-to-follow-up" for the survival analysis, bring up the "lost-to-follow-up" percentage to 9.5%. The FDA analysis which follows the applicant's analysis censored 6.5% of patients."

And the following sentence should be changed from:

"The number of deaths were greater on the atrasentan arm (atrasentan N=166, 57.3%; and placebo N=158, 56.6%)" to "The number of deaths were greater on the atrasentan arm (atrasentan N=166, 41%; and placebo N=158, 39%)"

3. Page 90: Correct the following typographical error in last paragraph:

Change "One of the retrospectively identified subsets with favorable results, i.e., patients with no bone metastases at baseline was chosen by the applicant as the primary basis for efficacy six months into the review of this NDA." to "One of the retrospectively identified subsets with favorable results, i.e., patients with bone metastases at baseline was chosen by the applicant as the primary basis for efficacy six months into the review of this NDA."

4. Page 93: Remove the following sentence from the first paragraph:

"This protocol was not submitted to the FDA prior to the NDA."