Reviewer's report

Title: Comparison of darbepoetin alfa dosed weekly (QW) vs. extended dosing schedule (EDS) in the treatment of anemia in patients receiving multi-cycle chemotherapy in a randomized, phase 2, open-label trial

Version: 1 Date: 16 November 2009

Reviewer: Xue Song

Reviewer's report:

Referee report on Schwartzberg et al. paper

This paper describes the results of a clinical trial that examines the noninferiority of extended dosing schedule versus weekly dosing schedule for darbepoetin alfa in cancer patients with chemotherapy-induced anemia. The paper is well written and well designed but there are some sections that can be improved:

Minor Essential Revisions

1. Methods in Abstract: The first sentence could be revised to include the treatment arms in the comparison, such as “This phase 2, 25-week, open-label study evaluated the noninferiority of extended dosing schedule versus weekly dosing schedule of darbepoetin alfa in patients with CIA.”

2. Provide the start and end month and year of when this clinical was conducted.

3. 95% CL was first mentioned on page 8 but the full description of 95% CL was not given until page 11.

4. The last sentence of the first paragraph on page 11, “Analysis of individual strata with large sample sizes showed a similar lack of differences between treatment groups.” It would be interesting to list the individual strata that were examined.

5. The title of table 1 should be “Patient demographic and clinical characteristics.” It will be interesting to report the mean length of chemotherapy cycle in both treatment arms as chemotherapy cycle length was controlled for in the estimation of change in hemoglobin from baseline to Week 13 (page 11). It will also be interesting to report the chemotherapy cycle distribution in the EDS arm.

6. Figure 3. Is there a footnote for superscripts a & b?

7. Figure 5. Is there a footnote for superscript a in “Difference (95% CL)”?

Discretionary Revisions

1. The results section in the abstract can also include findings on transfusions since transfusion is a secondary endpoint.

2. Table 1-4. Can authors provide p values of statistical tests that compare the QW and EDS arms?
Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.