Reviewer's report

Title: Phase II study of two dose schedules of C.E.R.A. (Continuous Erythropoietin Receptor Activator) in anemic patients with advanced non-small cell lung cancer (NSCLC) receiving chemotherapy

Version: 1 Date: 27 November 2006

Reviewer: Allan Donner

Reviewer's report:

General

This is well-written methodically strong paper which will serve as a useful addition to the literature provided the points raised below are addressed.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. For the sample size provided on page 11, more detail as to its derivation, or at least an appropriate reference, should be provided.

2. Some discussion as to why the summary measure AUC was chosen as the primary measure of efficacy in this study, rather than other possible choices, such as the final value, average of the last two visits, final value-initial value, etc., would be valuable.

3. In the section on Statistical Analyses it is stated that ANOCOVA will be used to analyze the primary efficacy variable, while in the results provided on page 14 the analyses are presented instead in terms of mean change from baseline. This should be clarified.

4. The authors present separate analyses for the different dose groups. Given the doses are ordered, would it not be more powerful to perform a trend test across these groups? This would also have the advantage of reducing the multiplicity problems caused by the construction of separate confidence intervals.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

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Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.