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: 23 September 2006

Reviewer: Robert Pirker

Reviewer's report:

General
The paper reports on a randomized phase II dose-finding study of CERA for the treatment of anemia in patients with advanced non-small cell lung cancer (stages IIIB & IV). The trial evaluated CERA administered either weekly or 3-weekly and at each schedule with 3 different doses. The authors found a dose-dependent effect of CERA on the increase of Hb levels at both schedules and on the proportion of patients achieving a hematopoietic response.
CERA was well tolerated. The findings are of clinical relevance. The data are well and thoroughly presented and the paper is well written.

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

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

Discretionary Revisions (which the author can choose to ignore)
1) The authors should specify IIIB which most probably refers to “wet” IIIB only.
2) Background: The authors mention chemotherapy as part of the management of stage III-IV NSCLC. They might mention that radiotherapy is added to chemotherapy in patients with stage III (N2 -3). Alternatively, they might specify stage III as “wet stage IIIB” where no radiotherapy is added.
3) Exclusion criteria: malignancy of the CNS: “brain metastasis” might be more appropriate.
4) Study design: “..where patients received CERA over a 12 week-treatment period…” change to “…where patients were planned to receive CERA over a …”
5) Page 9: what does appropriate clinical intervention refer to?

What next?: Accept after discretionary revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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