Reviewer's report

Title: An Open-label, Sequential, Dose-finding Study of Peginesatide for the Maintenance Treatment of Anemia in Chronic Hemodialysis Patients

Version: 1 Date: 31 May 2012

Reviewer: Lucia Del Vecchio

Reviewer's report:

1. Is the question posed by the authors well defined? YES
2. Are the methods appropriate and well described? YES
3. Are the data sound? YES
4. Does the manuscript adhere to the relevant standards for reporting and data deposition? NO
5. Are the discussion and conclusions well balanced and adequately supported by the data? YES
6. Are limitations of the work clearly stated? YES
7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
8. Do the title and abstract accurately convey what has been found? NO
9. Is the writing acceptable? YES

The paper deals with the results of phase II development of a new ESA that has been recently approved for clinical use in dialysis patients in the US. Altogether the findings are of interest; the study design, even if quite complicate, is reasonable.

However, data presentation is suboptimal.

In particular:
- Abstract section, results: some numeric data should also be given, no information is given about study follow-up, number of enrolled patients and administration route. Conversely the background is too long, methods are vague.

Key-words: epoetin alfa should be added

Conflict of interest: the authors should give all their interests in the field of anemia

Introduction: the authors should better explain the molecular structure of peginasitide and give information about its pharmacodynamic and pharmacokinetic.

Results: please specify the administration route of the two drugs.

Results; efficacy: main numeric data should be given also in the text Statistical analysis: even if this was a pre-specified analysis, the use of a target Hg range of 9.5-13.00 is too large (considering that patients started with a Hb range of
10-12.5 g/dl). Information about how many patients remained in the initial range should be given. The rational of using a second Hb range (11-13) is unclear (considering that this was not pre-specified by study protocol) and does not reflect current recommendation of international guidelines.

Discussion: mean serum ferritin and TSAT appears quite high. Please discuss this point.

Discussion: neutralizing antibodies. This information should be reported in the result section.