Reviewer's report

Title: Phase 1 safety and tolerability study of BMP-7 in symptomatic knee osteoarthritis.

Version: 1 Date: 22 July 2010

Reviewer: Janette Furuzawa-Carballeda

Reviewer's report:

The study by Hunter DJ et al. evaluated the safety and tolerability as well as dose-limiting toxicity and maximal tolerated dose of intra-articular BMP-7 administration. Clinical laboratory tests, immunogenicity data and radiographic assessments were also included in this study.

Major Compulsory Revisions.

1. Please explain any abbreviation used in the text, for example AP, OP-1 and AE. Not each reader may be familiar with these abbreviations.

2. Section of Test product, dose and mode of administration, requires an extensive revision because is very redundant.

3. How do the authors measure immunogenicity? It does not explain in the materials and methods. Why the immunogenicity results are not mentioned in the results section?

4. Why the results of urinalysis, hematology, chemistry, and biomarker assessments are not mentioned in the results section?

5. Were patients provided with instructions on a set of standard physiotherapy exercises to be performed throughout the study?

6. Explain the rationale to use only one administration of BMP-7.

7. Why authors are not mentioned if there were modifications in joint space narrowing, osteophytes and cartilage evaluated by X-ray?

8. In table 1 please add, disease duration as well as analgesic usage or concomitant medication (tablets/day) and range in all the evaluations.

Minor Essential Revisions:

The article will be greatly enhanced by including the following references in the next revision:

1) Furuzawa-Carballeda J, Muñoz-Chable OA, Barrios-Payán J,


Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

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