Reviewer’s report

Title: Preclinical and clinical phase I studies of a new recombinant Filgrastim (BK0023) in comparison with Neupogen(R).

Version: 2 Date: 2 December 2013

Reviewer: Pedro Gascon

Reviewer’s report:

This is a manuscript that deals with the preclinical and clinical phase of a new biosimilar BK0023, of Filgrastim (Neupogen). It is well designed and written. The manuscript and the experiments follow a standard procedure and the authors do it in an elegant, clear way.

The results are clear, robust and convincing: by western blottin, RP-HPLC, SE-HPLC, amino acid sequence and peptide mapping, radioligand-binding assay, immunoenzymatic analysis, toxicity tests in rats and in rabbits and the phase 1 in normal healthy volunteers (men). Chemically, biologically and clinically the biosimilar BK0023 is very similar to the originator Filgrastim-Neupogen.

Statistical analysis are correct

Comments

1. Background-abstract, page 1: "...mobilize therapeutic hematopoietic progenitors CD34 positive (CD34+)..cells from the bone marrow to the peripheral blood.

Although CD34+ can be pro-angiogenic, the reason for Filgrastim is to mobilize hematopoietic progenitors to correct the neutropenia. Also, although morphologically they are mononuclear cells in hematology this sentence is not reserved to hematopoietic progenitors, So, it would be more accurate to re.write this sentence in a way similar as .above

2. Table 6. Since the difference in BK0023 for 10ug/Kg and Neupogen 10ug/Kg is important: 51 vs. 14; 2 vs. 1; and 179 vs. 65". the authors should add some explanation in the text

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.

Declaration of competing interests:

I have no financial interests in the products described in the manuscript or in any non-financial interests either