Reviewer's report

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

Version: 2  Date: 23 December 2013

Reviewer: Jonathan Hoggatt

Reviewer's report:

Major Comments

1.) In the abstract, the authors mention that G-CSF mobilizes "therapeutic pro-angiogenic CD34 positive cells". While this may be true, this is an odd statement... the primary purpose of CD34 mobilization with G-CSF is cells of hematopoietic reconstituting ability for bone marrow transplantation. This wording should be changed to reflect that.

2.) Similarly, in the discussion, the authors make claims about G-CSF use in coronary disease and neurogenesis. This again is on the fringe of CD34 mobilization and is not reflective of the approved uses for the current test compound, filgrastim (Neupogen). The discussion should be changed to reflect the current standard of care in the mobilization of CD34.

3.) Given the abstract and discussion points on G-CSF mobilization of CD34 it is surprising that the authors did not compare the ability of BK0023 to mobilize CD34 compared to Neupogen. This parameter is commonly reported for biosimilar studies of G-CSF, i.e. that reported with Zarzio in Ann Oncol. 2010 Jul;21(7):1419-29 Do the authors have CD34 data in the healthy volunteer studies? If not, then discussion of CD34 mobilization most likely should be omitted from this particular report.

Minor Comments

1.) While there is some information in the Figure legends, the authors should put legends in the actual graphical images of the figures denoting which line is which compound (solid versus dashed; circle versus square, etc.)

2.) The manuscript could use editorial work to clean up the English.

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

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

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:

I declare that I have no competing interests