Reviewer’s report

Title: Efficacy and safety of RGB-02, a Pegfilgrastim Biosimilar to prevent Chemotherapy-Induced Neutropenia: Results of a Randomized, Double-Blind Phase III Clinical Study vs. Reference Pegfilgrastim in Patients with breast cancer receiving chemotherapy

Version: 0 Date: 18 Nov 2018

Reviewer: John Hilton

Reviewer’s report:

Well written manuscript with only one concern which is likely easily addressed.

Primary endpoint of duration of severe neutropenia is going to be dependent on when it was detected. Not clear in methods whether or not mandatory blood draws were done at certain time points or not, or whether or not it was physician discretion. If it was not done at set time points, then the primary endpoint is potentially biased as the starting point for detection of severe neutropenia could potentially vary from patient to patient.

I suspect from figure 2 that it was a set time points. The time points for blood draws needs to be clearly added to the methods.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Unable to assess

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If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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