Author’s response to reviews

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

Authors:
Zsuzsanna Kahan (kahan.zsuzsanna@med.u-szeged.hu)
Daniela Grecea (danagrecea@yahoo.com)
Martin Smakal (msmakal@gmail.com)
Sergei Tjulandin (stjulandin@gmail.com)
Igor Bondarenko (oncology@dsma.dp.ua)
Luca Perjesi (perjesil@richter.hu)
Andras Illes (andras.illes@richter.hu)
Karoly Horvat-Karajz (horvatkarajz@richter.hu)
Ildiko Aradi (i.aradi@richter.hu)

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Author’s response to reviews:

Dear Akila Sridhar, Linda Gummlich and Editorial Office of BMC Cancer,

On behalf of the Study Group, I would like to thank you very much for your and the peer reviewers’ valuable comments and recommendations, which, we are convinced that further improve the quality of the manuscript.

I am pleased to submit for your consideration the updated manuscript titled, “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.”

In line with the recommendations, the following modifications has been made:

• Background section, lines 66-68, page 3: The sentence is re-worded as requested.
As a response to Dr Makoto Kubo’s note on the pharmacokinetics of G-CSF, the authors confirm that serum pegfilgrastim concentration was not measured in the Comparative Efficacy and Safety study. During the development of RGB-02, healthy volunteer studies have been conducted to compare the pharmacokinetic and pharmacodynamic properties of RGB-02 to the originator product, Neulasta. The results of these healthy volunteer studies do not fall within the scope of the current manuscript and are planned to be published later in separate publications.

In addition to the recommended changes, the only change made by the authors is that the planned brand name (i.e. Efgratin) of RGB-02 has been deleted, since RGB-02’s marketing authorization has not yet been granted.

Thank you for your consideration.

Sincerely yours,

Andras Illes MD PhD