Author’s response to reviews

Title: Rationale and design of the German-Speaking Myeloma Multicenter Group (GMMG) trial HD6: A randomized phase III trial on the effect of elotuzumab in VRD induction/consolidation and lenalidomide maintenance in patients with newly diagnosed myeloma

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**Version: 4  Date: 06 Mar 2019**

**Author’s response to reviews:**

Dear Dr. Gummlich,

First of all thank you for giving us the opportunity to revise our paper “Rationale and design of the German-Speaking Myeloma Multicenter Group (GMMG) trial HD6: A randomized phase III trial on the effect of elotuzumab in VRD induction/consolidation and lenalidomide maintenance in patients with newly diagnosed myeloma”.

Listed below please find our detailed responses to the reviewer’s comments:

1. **Your finding:**

   It has come to our attention that within your manuscript there is significant text overlap with other publications, particularly:


   - Mateos, Maria-Victoria, et al. "Phase 3 randomized study of daratumumab plus bortezomib, melphalan, and prednisone (D-VMP) versus bortezomib, melphalan, and prednisone (VMP) in

Our reply:

We modified the text to the best of our knowledge so that there is no more direct overlap to the paper: Rationale and design of the German-speaking Myeloma Multicenter Group (GMMG) trial ReLApS-E: a randomized, open, multicenter phase III trial of lenalidomide/dexamethasone versus lenalidomide/dexamethasone plus subsequent autologous stem cell transplantation and lenalidomide maintenance in patients with relapsed multiple myeloma." BMC cancer 16.1 (2016): 290.

We did not find any overlap with the abstract: "Phase 3 randomized study of daratumumab plus bortezomib, melphalan, and prednisone (D-VMP) versus bortezomib, melphalan, and prednisone (VMP) in newly diagnosed multiple myeloma (NDMM) patients (Pts) ineligible for transplant (ALCYONE)." (2017): LBA-4.

2. Your finding:

Please format your abstract under the following headings:

- Background
- Methods
- Results
- Conclusions

Our reply: The abstract has been formatted.

3. Your finding:

Please rename Methods/design to Methods.

Our reply: Methods/design was named Methods.

4. Your finding:

Please ensure your TRN is clearly stated at the end of your abstract, within the manuscript.
Our reply: The Trial registration number: NCT02495922 is in the abstract.

5. Your finding:

Please add a “Conclusions” section after the “Discussion” section. This should state clearly the main conclusions of the research article and give a clear explanation of their importance and relevance.

Our reply: A Conclusion section has been added after the Discussion section.

6. Your Finding:

In the “Funding” section of your declarations, please clarify the role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Our reply: In the funding section on page 12 we added:

Funding

The GMMG HD6 trial is supported by grants from Bristol Myers Squibb, Chugai and Celgene. A peer review of the study protocol was done by the companies. Influence of the sponsors: This is an investigator initiated study. The study design was developed with the Department of Biostatistics at the German Cancer Research Center, Heidelberg, see section "Statistical analysis". The study design was discussed with the sponsors, who had accepted the IIT design.

7. Your Finding:

Thank you for providing your SPIRIT checklist and cover letter. However, at this stage it is not required and so we kindly ask that you remove it from your manuscript.

Our reply: We will not provide the SPIRIT checklist with this revised manuscript.

With many thanks and kind regards

Hans Salwender