Author’s response to reviews

Title: A randomized, placebo-controlled clinical trial evaluating the safety and efficacy of the once-weekly DPP-4 inhibitor omarigliptin in patients with type 2 diabetes mellitus inadequately controlled by glimepiride and metformin

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Dear Anne Menard,

Thank you for your suggested revisions to BEND-D-17-00095R2, “A randomized, placebo-controlled clinical trial evaluating the safety and efficacy of the once-weekly DPP-4 inhibitor omarigliptin in patients with type 2 diabetes mellitus inadequately controlled by glimepiride and metformin.” Below please find our responses to your suggestions.
Comment 1: Please include the full name of the ethics committee (and the institute to which it belongs to) that approved the study and the committee’s reference number if appropriate. Please include this information in the Ethics approval and consent to participate section.

Response to Comment 1: The ‘Ethics approval and consent to participate’ section now states:

The study (MK-3102-022; NCT01704261, EudraCT: 2012-002612-10) was conducted in accordance with the principles of Good Clinical Practice. Independent Ethics Committees (IECs) reviewed and approved the protocol and applicable amendments (see Appendix 1). Informed consent was obtained from all study participants.

Appendix 1:

International Ethics Committees (IEC’s) by Country:

Poland Komisja Bioetyczna przy Okregowej Izbie Lekarskiej w Gdańsku, Gdansk 80-204 Poland. Republic of Korea Gachon University Gil Medical Center, Namdong-Gu Incheon 405-760 Republic of Korea; CHA Bundang Medical Center, CHA University, Seongnam-si, 487-010 Republic of Korea; EWHA Womans University Hospital, Seoul 158-710 Republic of Korea; Yonsei University College of Medicine, Seoul 120-752 Republic of Korea; The Catholic University of Korea, Seoul St. Mary's Hospital, Seoul 137-701 Republic of Korea. Romania Comisia Naţională de Bioetică a Medicamentului şi a Dispozitivelor Medicale, Bucuresti 020125 Romania. Russian Federation Nizhny Novgorod Regional Clinic, Nizhny Novgorod 603126 Russian Federation; Saratov State Medical University n.a. V.I. Razumovsky of Ministry of Health of Russia, Saratov 410012 Russian Federation; Kazan State Medical University Ministry of Health of Russia, Kazan, Republic of Tatarstan 420043 Russian Federation; Expert Council on Biomedical Ethics under Bashkir State Medical University of Ministry of Health of Russia, Ufa 450071 Russian Federation. South Africa Pharma-Ethics Independent Research Ethics Committee, Lyttelton Manor Gauteng 0157 South Africa. United States Schulman Associates Institution, Cincinnati, OH 45242.

Comment 2: The individual contributions of ALL authors to the manuscript should be specified in the Authors’ Contributions section. We note that you have stated that "All authors were involved in at least one of the following", please note that to qualify for authorship, according to the ICMJE guidelines, an author one should have:

a) made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; AND
b) been involved in drafting the manuscript or revising it critically for important intellectual content; AND

c) given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; AND

d) agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Response to Comment 2: The Author Contribution section now includes details of the individual contributions of each author. (All authors meet the ICMJE authorship guidelines.)

S-HL, IG, ER, ML, EAON, PC, SS, KDK, SSE, and EL are responsible for the work described in this paper. IG, ER, ML, SS, KDK, SSE, and EL conceived, designed, and/or planned the study. S-HL acquired the data. PC analyzed the data. S-HL, IG, ER, EAON, PC, SS, KDK, SSE, and EL interpreted the results. IG and EAON, drafted the manuscript. S-HL, IG, ER, ML, PC, SS, KDK, SSE, and EL critically reviewed and/or revised the manuscript for important intellectual content. All authors provided final approval of the version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Comment 3: Please include the date that the trial was registered in the Trial Registration section, including whether the trial was registered retrospectively (if not, you do not need to state that it was prospectively registered).

Response to Comment 3: The trial was registered October 8, 2012 (and last updated June 5, 2017). This information was added to the Trial Registration section.