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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Author’s response to reviews:

Dear Dr. Yabe,

We are pleased that Professor Saisho is satisfied by our response to his review.

Thank you for the opportunity to reply to Professor Nakamura’s follow-up query. Please see our response below.

Akinobu Nakamura (Reviewer 2): The authors revised their manuscript according to the criticisms. There is, however, one point which should be addressed for publication in this journal.
Specific comments

Major points

Criticism 1: (Discussion) "The relative increase in body weight in the omarigliptin group compared to placebo may be due to the improvement in glycemic control and better metabolic status of the patients treated with omarigliptin." I do not understand this sentence. Why could the improvement in glycemic control and better metabolic status increase body weight? The phrase "better metabolic status" is too vague.

Response

The body weight in the omarigliptin group did not go up; the change from baseline was -0.1 kg. The change from baseline in the placebo group was -0.9 kg. The fact that there was less weight loss in the omarigliptin group compared with the placebo group may be due to the improvement in glycemic control in patients treated with omarigliptin, such that patients were not losing as much glucose (calories) in their urine relative to the placebo group. We agree with Professor Nakamura that the use of the phrase “better metabolic status” may be vague; therefore per his request we have revised the sentence in the manuscript as follows:

“The smaller weight loss in the omarigliptin group compared to placebo may be due to the improvement in glycemic control and attendant reduction in glycosuria-related calorie loss of the patients treated with omarigliptin.”

Sincerely,

Ira Gantz, M.D.