Reviewer’s report

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

Version: 0 Date: 04 May 2017

Reviewer: Akinobu Nakamura

Reviewer's report:

Authors investigated the glycemic efficacy and safety of once-weekly DPP-4 inhibitor omarigliptin when added to treatment of patients with inadequate glycemic control on the combination of metformin and glimepiride. This prospective randomized study showed that once-weekly omarigliptin provided greater improvement in glycemic control and was generally well-tolerated. This study was well designed and this manuscript was written accurately and concisely. There are, however, a few points which should be addressed for publication in this journal.

Specific comments

Criticism 1: (Results) "At Week 24, the change from baseline in body weight (LS mean [95% CI]) was -0.1 kg [-0.7, 0.4] in the omarigliptin group and -0.9 [-1.4, -0.4] in the placebo group; between-group difference = 0.8 kg (0.1, 1.5)." This result indicated that a significant increase in body weight in the omarigliptin group compared with that in the placebo group was observed. Authors should discuss this result in more detail.

Criticism 2: (Statistical Analyses) Line 27: "Each patient was categorized as a responder (satisfying the HbA1c specific goal of <7.0% or <6.5% or non-responder at Week 24." There is no ending parenthesis.

Criticism 3: Please add the word "AHA" into the Abbreviation list.

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

Yes

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.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

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

Acceptable

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