Reviewer’s report

Title: Efficacy and safety of olanzapine for treatment of patients with bipolar depression: Japanese subpopulation analysis of a randomized, double-blind, placebo-controlled study

Version: 1 Date: 18 November 2012

Reviewer: Hiroyuki Uchida

Reviewer’s report:

In this study, the authors performed a post-hoc analysis of Japanese patients from a 6-week, global DBRCT, Phase 3 study of patients with a depressive episode of bipolar I disorder. Patients in the olanzapine group experienced greater improvement in the primary outcome MADRS total score as well as those in other scales, and the authors concluded that the results supported the efficacy and tolerability of olanzapine in the treatment of Japanese patients with bipolar depression.

This is well-written, and I hope that the following minor comments will improve the quality of this relevant report.

Major Compulsory Revisions

Introduction
(1) The rationale of this additional analysis seems weak, which should be further emphasized. Otherwise, this would be regarded as another boring post-hoc analysis paper.

Methods:
(2) Mention to MMRM should be included here.

Discussion:
(3) The paragraph that begins with “Of note,” is not necessary. This is not based on the results of this study.
(4) Statistically significant differences in outcome measures were found between OLZ and PLB; however, the differences are numerically minor. Pls fairly discuss clinical relevance of those statistically significant but minor differences.
(5) The paragraph that begins with “The results in the Japanese population…” should be removed. This is not based on the results of this study.

Minor Essential Revisions

Discretionary Revisions
None

Level of interest: An article whose findings are important to those with closely related research interests
**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

Dr. Uchida has received grants from Pfizer, Astellas Pharmaceutical, Eisai, Otsuka Pharmaceutical, Pharmaceutical, GlaxoSmithKline, Shiohogi, and Dainippon-Sumitomo Pharma, Eli Lilly, Mochida Pharmaceutical, Meiji-Seika Pharma, Janssen Pharmaceutical, and Yoshitomi Yakuhin and speaker’s honoraria from Otsuka Pharmaceutical, Janssen Pharmaceutical, Novartis Pharma, Eli Lilly, Shionogi, GlaxoSmithKline, Yoshitomi Yakuhin, Dainippon-Sumitomo Pharma, and Janssen Pharmaceutical.