Reviewer's report

Title: Fingolimod (FTY720) in Japanese patients with relapsing multiple sclerosis: 12-month results of a phase 2 extension study

Version: 2 Date: 23 August 2013

Reviewer: Robert Bermel

Reviewer's report:

The authors describe the results of an extension study conducted in Japan of patients with MS initially randomized to fingolimod or placebo, then switched to fingolimod and followed in a systematic extension study, with safety follow-up, clinical and MRI outcomes.

Strengths of this manuscript include:
1. Excellent retention into the follow-up study (>97%).
2. Clearly written
3. Appropriate tables and figures
4. Appropriate balance between efficacy and safety data
5. Very useful description of the outcome of patients identified to be NMO-IgG positive who had been on fingolimod in the course of the study.

Minor essential revisions:
1. While the conclusions are generally supported by the data, statistical analysis (hypothesis tests with p-values) should be performed and included for the tables and figures, so that the reader can judge (especially given the small sizes of some of the groups) the significance of differences between the groups and the overall results.
2. Additional description needed in the body of the manuscript about the one death, specifically the duration that he was treated with fingolimod, and whether this was determined to be a death related or unrelated to the study medication (the supplemental material seems to suggest that lymphoma was the original correct diagnosis prior to study randomization, and that the patient did not actually have MS??)

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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

Declaration of competing interests:
Research and consulting fees from Novartis.