Reviewer's report

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

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Reviewer: Tereza Gabelic

Reviewer's report:

Interesting and thought provoking paper, however there is one important fact that I would point as

Major Compulsory Revisions: the lack of statistical analysis.

All data are given in descriptive form without doing statistical analyses between groups. Without statistical testing, it is impossible to draw any conclusions about drug efficiency. For all the reader knows, the presented results are due to random error. In addition, given the fact that statistical analysis were initially reported for original core paper (Reference number 10), I don’t quite understand why the authors did not do the same for this manuscript. Authors should either conduct analyses, or provide a very detailed explanation for not doing statistical analysis. All in all, the general problem lies in that several claims are made based on the results, but without statistical confirmation, those cannot be made.

These include “Baseline MS disease characteristics of the extension randomized population were

generally similar across treatment groups (Table 1) with the exception of mean number of

relapses in the previous 1 or 2 years and the proportion of patients free of Gd-enhancing

lesions”, or “In patients switched from placebo to fingolimod therapy, inflammatory MRI activity was reduced in the extension study compared with the core phase, with consistent effects across the two fingolimod doses (Table 2)” and “Infections and infestations were the most commonly reported AEs and occurred in generally similar proportions of continuously treated and switched patients, but were slightly more common in the fingolimod 1.25 mg groups than the 0.5 mg groups (Table 3)”.

- Minor Essential Revisions

Patients with NMO:

It is not clear at what point the authors became aware of NMO serology positive results. According to disease course described in supplemental material at the end of manuscript, there were some radiological findings that could point to alternative diagnoses. Could the authors comment why these patients were not excluded before from the study?
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I have nothing to declare