Reviewer’s report

Title: A randomized placebo-controlled trial of delayed-release dimethyl fumarate in patients with relapsing-remitting multiple sclerosis from East Asia and other countries

Version: 1 Date: 15 May 2018

Reviewer: Emanuele D'Amico

Reviewer's report:

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This randomized placebo-controlled trial of delayed-release dimethyl fumarate showed the efficacy and favorable benefit-risk profile of DMF for Japanese, and more broadly, East Asian patients with RRMS.

About the randomization process I have some concerns about the inclusion of RRMS with EDSS higher than 4.0; some of SPMS in my opinion. I'd like to see analyses about the population over 3.5 of EDSS, as the mean (EDSS should be expressed in median value) in the groups of study is about 2.0.

As second major concern we have no data about any treatment of Gd+ lesions at baseline. If a patient got steroids for a positive MRI, I expect that in 24 weeks the effect on such lesions is due to the steroids and not to the investigation drug.

Moreover, could be useful provide a NEDA 3 composite of described results. Yes, in my opinion.

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?
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Yes
Are the conclusions drawn adequately supported by the data shown?  
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