Reviewer's report

Title: Infliximab for pediatric patients with ulcerative colitis: a phase 3, open-label, uncontrolled, multicenter trial in Japan

Version: 0 Date: 13 Jul 2019

Reviewer: Ryuta Nishikomori

Reviewer's report:

The authors performed the first phase 3 trial to evaluate the efficacy, safety, and pharmacokinetic profile of infliximab in Japanese pediatric patients with moderate-to-severe UC who have not been treated adequately with current therapy. The study was performed nicely and the authors demonstrated the efficacy of infliximab in these pediatric UC patients, although the study was not that novel. I would like to ask a couple of questions on the study.

1) In table 2, the IFX concentration on week 14, 22, and 30 of 6 to 12 years seemed to me less than those of 12 to 17 years. Did the authors evaluate it statistically?

2) I would like to know the incidence of the secondary failure of the infliximab in these patients.

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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