Reviewer's report

Title: A Multicentre, Randomized, Double-blind Study Comparing Different FK778 Doses (Manitimus) with Tacrolimus and Steroids vs. MMF with Tacrolimus and Steroids in Renal Transplantation

Version: 1 Date: 16 December 2011

Reviewer: Tobias Deuse

Reviewer's report:

Major Compulsory Revisions
1) Study design: The authors should comment why 3 different groups of FK778 were chosen with overlapping target trough levels. One could have assumed that only very minor differences between groups would become apparent.
2) Results: The number of patients that achieved target FK778 levels within each group should be mentioned.
3) Table 3: It is unclear how the numbers of treatment outcome (steroid resistant/steroid sensitive) are related to the BPAR at 12 months, because the numbers don’t add up.
4) Discussion: Although it is stated on page 10 that “The incidence of treatment failure at 12 months … was comparable between low level [FK778] and MMF…” the authors conclude that “the incidence of treatment failure in our study was lower with MMF than with low level FK778”. That latter statement is not supported by the data.

Minor Essential Revisions
1) I would suggest to more thoroughly discuss the surprising results of achieving less efficacy with higher doses of FK778 in this trial, although previous experimental data showed stronger immunosuppression by higher doses.

Discretionary Revisions
1) The manuscript should be carefully shortened and redundancy should be omitted.

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.