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: 19 December 2011

Reviewer: Lisa McDevitt

Reviewer's report:

Minor essential revisions:

Please explain why the authors chose an MMF dose of 1g/day (i.e. rather than the standard 1g BID) for the control arm.

The authors state that a dose-finding study indicated that FK778 plasma concentrations >100 mcg/ml may be most efficacious yet in the present study, one of the groups had target trough levels of 50-100 mcg/ml. Please explain the choice to use this low target range when the dose-finding study suggested otherwise.

Please comment on the mechanism (or theoretic mechanism) behind the apparent tacrolimus:FK778 drug interaction.

Discretionary revisions:

In discussing the proof of concept clinical trial (ref 7), the authors state that target plasma FK778 levels were hard to achieve in the early phase after transplantation. Please add a comment explaining why (i.e. were the levels achieved generally too high or too low?).

With the inclusion/exclusion criteria, please clarify whether ECD or DCD donors were allowed and whether subjects were 1st transplant only or whether repeat renal transplant recipients were allowed.

Results paragraph 1 – please correct to “WERE due to adverse events…”

Were all pairs truly ABO identical? or were non-identical but ABO-compatible transplants allowed?

Define HBV positive. Were these surface antigen positive?

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the
statistics.

Declaration of competing interests:

I have received research support from Astellas in the past five years, but am not receiving such support currently.