Reviewer's report

Title: Modeling Dose-Response Relationships of the Effects of Fesoterodine in Patients With Overactive Bladder

Version: 1 Date: 7 January 2010

Reviewer: Giacomo Novara

Reviewer's report:

The authors reported a study evaluating the dose-response relationship in a pooled analyses of 2 phase II and 2 phase III study on Fesoterodine. The study finally demonstrated that dose-response relationship did exist.

The study is extremely complex and its methodology is impossible to understand for all the average readers of the Journal.

Introduction: in the second paragraph of the second page of the Background section, the statement “Therefore, mathematical models were developed to describe quantitative and predictive dose-response relationships of the effects of fesoterodine using a rich, subject level longitudinal data set from the phase II and III studies. This model-based dose-response characterization is more comprehensive because all available subject-level data obtained at each study visit after administration of 3 different dose levels (4 mg, 8 mg, or 12 mg) in the phase II and III trials were combined and analyzed.” can be deleted.

In the Results section and in table 2, it should be clarified if the predicted dose-response relationship yielded statistically significance.

The selection of postvoid residual urine as a parameter to evaluate the drug safety sounds a little bit inappropriate, due to the well known impact of anticholinergic drugs on the voiding phase of the micturition circle. Overall adverse event rate, withdrawal rates, or some specific complication rates would have likely been more appropriate.

In the “Postvoid residual volume” paragraph, please, add odds ratios, confidence interval, and p values for the significant covariates.

In the “Discussion” section, please assess the study limitations.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

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

No COY