Reviewer’s report

Title: Cardiac safety of indacaterol in healthy subjects: a randomized, multidose, placebo- and positive-controlled, parallel-group thorough QT study

Version: 1 Date: 4 April 2011

Reviewer: Heinrich Worth

Reviewer’s report:

The authors performed a well designed study on the effects of indacaterol in doses of 150 up to 600 µg/d on prolongation of the QT interval in healthy volunteers. Concerning the number of subjects under study, the doses of indacaterol chosen, as well as using moxifloxacin as positive comparator, the study was based on appropriate conditions.

The methods were adequate as well as the time schedule of QT analysis.

The data of this thorough QT study in over 400 healthy adults indicate, that indacaterol, at doses up to 600µg once daily, does not have any clinically significant effect on the QT interval. However, the data do not exclude effects of indacaterol in patients with heart diseases. Therefore, the authors could describe limitations of their results with respect to patients with COPD and cardiac comorbidities.

Spelling mistake: literature: no 9: non antiarrhythmic. …

I recommend the study for publication in BMC Pulmonary Medicine.

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

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.