Author's response to reviews

Title: Efficacy of mirabegron in patients with and without prior antimuscarinic therapy for overactive bladder: a post hoc analysis of a randomized European-Australian Phase 3 trial

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To whom it may concern:

Mirabegron is the first in a new class of agents—the β3 adrenoceptor agonists—developed for the treatment of overactive bladder (OAB) symptoms; it is now approved for the treatment of OAB in Europe, the United States, Japan and Canada.

We recently published the results of a Phase III 12 week registration study on mirabegron (Khullar et al. Efficacy and Tolerability of Mirabegron, a β(3)-Adrenoceptor Agonist, in Patients with Overactive Bladder: Results from a Randomised European-Australian Phase 3 Trial. Eur Urol. 2013 Feb;63(2):283-95.) Because the primary study enrolled patients who had previously taken antimuscarinic agents as well as those who were antimuscarinic treatment-naïve, we took the opportunity to conduct a post-hoc analysis of the primary data, evaluating the efficacy of mirabegron according to prior antimuscarinic use. The results are described in the paper submitted here, "Efficacy of mirabegron in patients with and without prior antimuscarinic therapy for overactive bladder: a post-hoc analysis of a randomised European-Australian Phase 3 trial".

Antimuscarinics are the mainstay pharmacological treatment for OAB although patients treated with antimuscarinics are known to frequently discontinue therapy due to an insufficient response to treatment or intolerable side effects, particularly dry mouth, constipation or blurred vision. Therefore, the need to devise treatments for patients who have discontinued prior antimuscarinics is a scenario likely to be encountered in clinical practice. For this reason, we believe that the findings of this post-hoc analysis provide some valuable insights and will be of particular interest to all physicians in the field.

The competing interests of all authors have been listed in a paragraph at the end of the paper. I can confirm that this paper has not been submitted elsewhere and look forward to hearing from you in due course.

Kind regards

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Reader in Urogynaecology