

CLINICAL TRIALS

MIRABEGRON FOR TREATING OAB

Mirabegron (Astellas Pharma Ltd, Tokyo, Japan) is a first-in-class therapy for overactive bladder (OAB) syndrome that has proven to be effective and well-tolerated in a recent phase III trial.

At 132 centres across the USA and Canada, adults with OAB symptoms for ≥ 3 months were randomized 1:1:1 to receive placebo, mirabegron 50 mg or 100 mg once daily for 12 weeks. Incontinence episodes, micturitions, voided volumes and urgency were recorded by the patient for 3 days prior to each check-up visit at weeks 4, 8 and 12. Compared with controls, mirabegron-treated groups demonstrated significantly greater mean decreases in the number of incontinence episodes and micturitions. They also reported improvements in urgency and nocturia, as well as symptom bother and health-related quality of life.

Currently, antimuscarinics are the only licensed oral treatment option for patients with OAB. These drugs bind to muscarinic receptors in the bladder and inhibit involuntary contractions. However, they also interact with other muscarinic receptor subtypes throughout the body, resulting in a range of adverse effects, including cognitive dysfunction. $\beta 3$ -adrenoceptor agonists such as mirabegron operate differently; they relax detrusor smooth muscle and increase bladder capacity. Encouragingly, adverse effects that are frequently associated with antimuscarinics—such as hypertension, headache, nasopharyngitis and UTI—were shown to be no more common in mirabegron-treated groups than in placebo-treated controls in the phase III trial. Dry mouth was reported in 1.5%, 0.5% and 2.1% of patients in the placebo, mirabegron 50 mg and 100 mg groups, respectively.

In light of this study, the Committee for Medicinal Products for Human Use of the European Medicines Agency has recommended that mirabegron be granted marketing authorization for the symptomatic treatment of OAB. Ratification of this decision by the European Commission is expected within the next 3 months. If approved, mirabegron will provide physicians and patients with a valuable alternative option to antimuscarinics, which are commonly discontinued owing to suboptimal efficacy and adverse effects.

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Original articles Nitti, V. *et al.* Results of a randomized phase III trial of mirabegron in patients with overactive bladder. *J. Urol.* doi:10.1016/j.juro.2012.10.017