The Potent and Selective β3-adrenoceptor Agonist Mirabegron Improves Patient-Reported Outcomes in the Treatment of Overactive Bladder

Introduction and Objectives: Mirabegron is a potent and selective β3-adrenoreceptor agonist for the treatment of overactive bladder (OAB). This analysis from a pivotal Phase III trial in patients with OAB in Europe and Australia reports the effect of mirabegron on patient-reported symptom bother, health-related quality of life (HRQoL) and treatment satisfaction.
Materials and Methods: This multicenter, randomized, double-blind, parallel-group, placebo- and active-controlled trial enrolled patients ≥18 years with symptoms of OAB for ≥3 months to a 2-week, single-blind, placebo run-in. Based on a 3-day micturition diary, patients with ≥8 micturitions/24 h and ≥3 urgency episodes/72 h (with or without incontinence) were randomized to receive placebo, mirabegron 50 or 100 mg, or tolterodine slow release (SR) 4 mg once daily for 12 weeks. The co-primary endpoints were changed from baseline to final visit (study end) in mean number of incontinence episodes and micturitions/24 h. Secondary endpoints included patient-reported outcomes (PROs) as assessed by the Overactive Bladder Questionnaire (OAB-q), Patient Perception of Bladder Condition (PPBC) and Treatment Satisfaction-Visual Analog Scale (TS-VAS).
Results: There were 1978 randomized patients who received study drug (placebo: n=494; mirabegron 50 mg: n=493; mirabegron 100 mg: n=496; tolterodine SR 4 mg: n=495). Mean age was 59.1 years, 72.2% were female, 39.5% had urgency incontinence, 37.8% had frequency without incontinence and 22.7% had mixed stress/urgency incontinence with urgency predominant. At the final visit, both mirabegron groups demonstrated statistically significant improvements in the co-primary endpoints as well as statistically significant improvements in secondary endpoints of PROs compared with placebo (Table).
Conclusions: In addition to improvements in key OAB symptoms, mirabegron (50 and 100 mg) was associated with statistically significant improvements compared with placebo in treatment satisfaction, symptom bother, HRQoL and patients' perception of bladder condition in this 12-week study of patients with OAB.

Efficacy Results: Adjusted mean *(standard error) for change from baseline at Final Visit			
Endpoints	**Placebo** (n=494)	**Mirabegron**	
		50 mg (n=493)	**100 mg** (n=496)
Co-primary endpoints			
No. incontinence episodes/24 h	–1.17 (0.113)	–1.57† (0.113)	–1.46† (0.115)
No. micturitions/24 h	–1.34 (0.110)	–1.93† (0.111)	–1.77† (0.110)
PRO secondary endpoints			
Treatment satisfaction (TS-VAS)‡	1.89 (0.146)	2.55& (0.149)	2.66& (0.146)
Symptom bother (OAB-q) ≠§	–14.9 (0.84)	–19.6& (0.85)	–19.9& (0.84)
HRQoL total score (OAB-q) ≠‡	13.7 (0.76)	16.1& (0.77)	17.0& (0.77)
PPBC§	–0.8 (0.05)	–1.0& (0.06)	–1.1& (0.05)

*Least squares mean adjusted for baseline, gender and geographical region; †p<0.05 vs placebo; ≠OAB-q subscale minimum important differences range from +5 to +12, denoting improved quality of life (HRQL) and −13 to −25, consistent with a reduction in symptom severity; ‡Positive change indicates improvement; §Negative change indicates improvement.
Note: Tolterodine results not shown