Study shows mirabegron effective and well tolerated for overactive bladder

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In a new phase III trial mirabegron, a β3-adrenoceptor agonist, given once daily for 12 weeks, reduced the frequency of incontinence episodes and number of daily urinations, and improved urgency and nocturia in adults with overactive bladder (OAB) compared to those in a placebo group. The incidence of common adverse events (hypertension, urinary tract infection, headache, nasopharyngitis) was similar in the mirabegron and placebo groups in this study. Rates of dry mouth and constipation were similar in the drug and placebo groups. The study is published in the *Journal of Urology*.

"Mirabegron is a first in class therapeutic agent with a mechanism of action distinct from that of antimuscarinic agents," says urologist Victor W. Nitti, MD, of the NYU Langone Medical Center. "While antimuscarinic agents are the current pharmacological mainstay for OAB, some patients have a suboptimal response or experience side effects such as dry mouth or constipation. The result is that a high proportion of patients on antimuscarinic drugs discontinue therapy, with only 25% remaining on therapy at one year. We need an alternative therapy for some of these patients."

This randomized, parallel group, double-blind phase III study comprising 1329 patients was conducted at 132 sites in the U.S. and Canada. Those eligible for the study voided 8 or more times daily and experienced 3 or more urgency episodes with or without incontinence over a 3-day period. After 2 weeks of receiving placebo, 454 patients were randomized to continue to receive placebo, 442 were given 50 mg mirabegron and 433

received 100 mg mirabegron daily for 12 weeks.

Compared to the placebo group, both mirabegron treatment groups showed statistically significant (p