

## FDA approves overactive bladder treatment from Astellas

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**Singapore:** The US Food and Drug Administration (FDA) has approved Myrbetriq (mirabegron) extended-release tablets for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency by Astellas Pharma.

"Myrbetriq is the first oral OAB treatment with a distinct mechanism of action since the launch of anticholinergic agents 30 years ago," said Dr Steven Ryder, president, Astellas Pharma Global Development. "The approval of Myrbetriq represents an important milestone in OAB treatment and in our ongoing commitment to advancing urological health."

Myrbetriq is a once daily oral beta-3 adrenergic agonist discovered and developed by Astellas. It has been studied extensively in more than 10,000 individuals over 10 years. Myrbetriq offers a new treatment option for patients with OAB. Antimuscarinics are the current OAB treatment standard.

Myrbetriq uses a distinct mechanism of action. Antimuscarinics work by binding to muscarinic receptors in the bladder and inhibiting involuntary bladder contractions. Myrbetriq relaxes the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle by activation of beta-3 adrenergic receptors which increases bladder capacity.

"OAB impacts each individual differently so it is important to have a variety of treatment options available," said Victor Nitti, MD, professor of Urology and Ob/Gyn, vice chairman, Department of Urology and director of Female Pelvic Medicine and Reconstructive Surgery NYU Langone Medical Center. "With Myrbetriq, U.S. physicians now have a new therapy option to offer many Americans living with overactive bladder."

The recommended starting dose for Myrbetriq is 25 mg once daily with or without food. Myrbetriq 25 mg is effective within eight weeks; based on individual efficacy and tolerability, the dose may be increased to 50 mg once daily. It was approved in Japan in July 2011, and regulatory applications are under review in several other countries.