

For Immediate Release

Astellas introduces Myrbetriq™, a new class of treatment for Canadian patients with overactive bladder

Myrbetriq is now available in pharmacies across Canada

April 10, 2013 – Markham, ON – Overactive bladder (OAB) is a chronic, debilitating condition that can have a profound, negative impact on a patient's quality of life.ⁱ Many patients with OAB are plagued by depression,ⁱⁱ experience a disruption in sleep,ⁱⁱⁱ limit their social activity,^{iv} and experience a loss of control and decreased self-esteem.^v

An estimated 2.9 million Canadian men and women^{vi} suffer from OAB symptoms^{vii}, which include:

- A strong, sudden urge to urinate
- The need to urinate more often than usual, usually more than eight times in a 24 hour period
- Waking up two or more times in the night to urinate (a condition called nocturia)
- Urge incontinence, the involuntary loss of urine immediately following an urgent need to urinate.

Astellas Pharma Canada, Inc., the Canadian subsidiary of Tokyo-based Astellas Pharma Inc., today announced the availability of Myrbetriq™ (mirabegron, extended-release tablets) for the treatment of OAB with symptoms of urge urinary incontinence, urgency and urinary frequency.^{viii} Myrbetriq is now available in pharmacies across Canada.

“Simply focusing on the treatment of OAB symptoms is not enough for patients,” says Dr. Blair Egerdie, BSc, MD, FRCSC, Investigator, Mirabegron Phase III trial and Vice President, Medical, St. Mary's General Hospital, Adjunct Professor of Urology at the University of Western Ontario. “We know OAB symptoms can be distressing; therefore, a focus on helping improve quality of life is critical. Everything from our patient's emotional well-being, to their productivity at work, mood, and social functioning can be affected. Treatment options that can help minimize this very real, very personal impact represent an important achievement in the treatment of OAB.”

Myrbetriq's distinct mechanism of action helps to increase bladder capacity by relaxing the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle.^{ix} This β 3-adrenoceptor agonist both reduces the activity of an overactive bladder as well as treats the related symptoms.^x

“Until now, when we've turned to medication to help with OAB symptoms, we've tried to block the chemical that causes bladder contractions,” explains Dr. Egerdie. “ β 3-agonists, however, essentially quiet an overactive bladder by relaxing the bladder, thereby increasing its capacity. Because OAB affects individuals so differently, these kinds of treatment options are extremely important to both physicians and patients.”

Myrbetriq was evaluated in three, 12-week, double-blind, randomized, placebo-controlled, parallel group, multicenter clinical trials in patients with OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency.

“Now that Myrbetriq is available through pharmacies, Canadian patients have access to the first new class of medication for the treatment of OAB in over 30 years,” said Michael Tremblay, President, Astellas Pharma Canada, Inc. “Astellas is committed to improving quality of life for patients living with overactive bladder, and we are pleased to add Myrbetriq to our portfolio of treatment options.”

About Myrbetriq^{xi}

Myrbetriq has been studied extensively in more than 10,000 individuals over 10 years.

The efficacy of Myrbetriq has been evaluated in three phase 3 randomized, double blind, placebo controlled, 12-week studies for the treatment of OAB with symptoms of urgency and frequency with or without incontinence. Entry criteria required that patients had symptoms of overactive bladder for at least three months duration, at least 8 micturitions per day, and at least three episodes of urgency with or without incontinence over a three day period. The majority of patients were Caucasian (94%) and female (72%) with a mean age of 59 years (range 18 - 95 years). The population included both naïve patients who had not received prior antimuscarinic pharmacotherapy for OAB (48%) and those who had received prior antimuscarinic pharmacotherapy for OAB (52%).

The co-primary efficacy endpoints in all three trials were (1) change from baseline to end of treatment (Week 12) in mean number of incontinence episodes per 24 hours and (2) change from baseline to end of treatment (Week 12) in mean number of micturitions per 24 hours, based on a three-day micturition diary.

The recommended starting dose for Myrbetriq is 25 mg once daily with or without food. Based on individual efficacy and tolerability, the dose may be increased to 50 mg once daily.

About Overactive Bladder

Overactive bladder (OAB) is a symptomatic condition marked by the sudden, compelling desire to pass urine that is difficult to defer.^{xii} This sudden urge to urinate, which is difficult to suppress, can lead to the involuntary loss of urine (incontinence).^{xiii} OAB occurs when the bladder’s smooth muscle, known as the detrusor muscle, involuntarily contracts, which creates the urgent need to urinate.^{xiv} Rushing to make it to the bathroom in time is common for people with OAB.

OAB symptoms occur in approximately equal numbers of men and women, and are more widespread in older patients of both genders.^{xv} Urge incontinence is the most common form of urinary incontinence in older adults, but it is not an inevitable consequence of aging and therefore can, and should, be medically treated.^{xvi}

OAB can greatly impact patients’ lives. Patients who have incontinence as a result of their OAB symptoms experience an even greater impact on their quality of life than those who do not experience incontinence.^{xvii}

About Astellas Pharma Canada, Inc.

Astellas Pharma Canada, Inc., headquartered in Markham, ON, is a Canadian affiliate of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global category leader in focused areas by combining outstanding R&D and marketing capabilities. In Canada, Astellas has an intense commercial focus on five therapeutic areas – Urology, Immunology, Infectious Disease, Dermatology and Oncology. For more information about Astellas Pharma Canada, Inc., please visit the corporate website: www.astellas.ca.

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^{iv} Ouslander, J. Management of Overactive Bladder. *The New England Journal of Medicine* (Review Article) 2004; 350:786-99.

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^{vii} Mayo Clinic. Overactive Bladder Symptoms. <http://www.mayoclinic.com/health/overactive-bladder/DS00827/DSECTION=symptoms>. Accessed on February 21, 2013.

^{viii} Myrbetriq™ Canadian approved Product Monograph, dated March 4, 2013.

^{ix} Myrbetriq™ Canadian approved Product Monograph, dated March 4, 2013.

^x Myrbetriq™ Canadian approved Product Monograph, dated March 4, 2013.

^{xi} Myrbetriq™ Canadian approved Product Monograph, dated March 4, 2013.

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^{xiii} Mayo Clinic. Overactive Bladder Definition. <http://www.mayoclinic.com/health/overactive-bladder/DS00827>. Accessed February 23, 2013.

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