

For Immediate Release

Astellas Pharma Canada, Inc. receives a Notice of Compliance from Health Canada for Myrbetriq™ (mirabegron)

March 8, 2013 – Markham, ON – Astellas Pharma Canada, Inc., the Canadian subsidiary of Tokyo-based Astellas Pharma Inc., announced today Health Canada's approval of Myrbetriq™ (mirabegron, extended-release tablets).

Mirabegron is indicated for the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence and urinary frequency.¹ Mirabegron, a selective β 3-adrenoceptor agonist, is a "first in class" therapeutic agent with a mechanism of action distinct from antimuscarinic agents², the current treatment standard for OAB. β 3-agonists relax the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle, which increases bladder capacity.³

Dr. Sender Herschorn is Professor of Urology at the University of Toronto, attending Urologist and Head of Urodynamics Laboratory at Sunnybrook Health Sciences Centre and the general secretary of the International Continence Society (ICS). He says many people who are experiencing overactive bladder simply suffer in silence because they are too embarrassed to discuss it with their physician.

"What these patients may not realize is that they don't just have to live with overactive bladder," said Dr. Herschorn. "There are good treatment options available that could significantly improve their overall quality of life."

Mirabegron, approved in Japan (July 2011), the US (June 2012) and Europe (December 2012), joins Vesicare (solifenacin succinate) in Astellas Pharma Canada's OAB portfolio.

"Myrbetriq is the first in a new class of medications for the treatment of OAB in over 30 years," said Michael Tremblay, President, Astellas Pharma Canada. "Urological health continues to be a key priority for Astellas and we are very pleased to be the first to offer Canadian patients a new treatment option."

CLINICAL TRIALS⁴

Myrbetriq was evaluated in three, 12-week, double-blind, randomized, placebo-controlled, parallel group, multicenter clinical trials in patients with overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. Entry criteria required that patients had symptoms of overactive bladder for at least 3 months duration, at least 8 micturitions per day, and at least 3 episodes of urgency with or without incontinence over a 3 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 overactive bladder (48%) and those who had received prior antimuscarinic pharmacotherapy for OAB (52%).

The co-primary efficacy endpoints in all 3 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 3-day micturition diary.

ABOUT OVERACTIVE BLADDER

Overactive bladder (OAB) is a common condition defined as urgency, with (OAB wet) or without urgency incontinence (OAB dry), usually associated with increased daytime frequency and nocturia.⁵ In a recent Canadian population-based study, OAB symptoms were reported in 13.9% of respondents (13.1% of men and 14.7% of women).⁶

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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FOR FURTHER INFORMATION:

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¹ Myrbetriq™ Canadian approved Product Monograph, dated March 4, 2013.

² Nitti, V., Auerbach, S., Martin, N., Calhoun, A., Lee, M., Herschorn, S., Results of a Randomized Phase III Trial of Mirabegron in Patients with Overactive Bladder, *The Journal of Urology*® (2012), doi: 10.1016/j.juro.2012.10.017.

³ Aizawa, N., Igawa, Y., Nishizawa, O. et al.: Effects of CL316,243, a beta 3-adrenoceptor agonist, and intravesical prostaglandin E2 on the primary bladder afferent activity of the rat. *Neurourol Urodyn*, 29: 771, 2010

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

^{5,6} Bettez M, Tu le M, Carlson K et al. *Can Urol Assoc J* 2012;6(5):354-63.