

**Solifenacin shows superior tolerability compared to oxybutynin immediate-release (IR)
Canadian study (VECTOR) presented at the 2009 American Urological Association Annual Meeting**

Chicago, Illinois, April 30, 2009 - Patients with overactive bladder (OAB) treated with solifenacin reported significantly lower incidence and severity of dry mouth, an often intolerable anti-cholinergic side effect, than those treated with oxybutynin immediate-release (IR). This was one of the key findings contained in the VECTOR (**VE**sicare in **C**omparison **T**o **O**xybutynin for ove**R**active bladder patients) study presented April 28, 2009 at the Late-Breaking Science Forum of the 2009 American Urological Association annual meeting in Chicago.

The VECTOR study compared the tolerability of solifenacin versus oxybutynin IR for the treatment of OAB. A secondary objective was to assess the efficacy of solifenacin versus oxybutynin IR for the treatment of OAB.

"Findings from the VECTOR study are very encouraging," said Sender Herschorn, MDCM, FRCSC, Professor and Chair of the Division of Urology at the University of Toronto and attending Urologist and Head of Urodynamics Laboratory at Sunnybrook Health Sciences Centre in Toronto, Canada. "The fact that some patients discontinue treatment for OAB because of intolerable side effects counters our best efforts to encourage them to seek treatment which could improve their quality of life. It is important for medical professionals, as well as the patients themselves, to be aware of treatment options to optimize the management of OAB."

Patients in the VECTOR study were adults over the age of 18 with OAB symptoms for ≥ 3 months (urgency with or without urinary incontinence, usually with frequency and nocturia) and as documented in a 3-day patient diary: > 1 urge episode / 24 hours (average) as well as ≥ 8 micturitions / 24 hours (average). Overall, 132 patients were recruited from 12 Canadian sites.

In this multi-centre, prospective, randomized, double-blind, double-dummy, 8 week study, solifenacin was associated with a superior tolerability profile compared to oxybutynin IR. Patients on solifenacin experienced a 48 per cent lower incidence of dry mouth and a lower severity of dry mouth, of which 75 per cent were mild, compared with patients taking oxybutynin IR ($p=0.001$). The findings also revealed significantly fewer withdrawals due to dry mouth as well as fewer overall adverse events ($p=0.009$), and fewer treatment related adverse events ($p=0.0093$) compared to oxybutynin IR. Both solifenacin and oxybutynin IR improved OAB symptoms and Patient-Reported Outcomes.

Solifenacin, a competitive muscarinic receptor antagonist, has not had its side effect profile directly compared with oxybutynin IR until this study. "It is hoped that these study results will make more people aware of a better tolerated treatment choice," said Herschorn.

About OAB

OAB is a chronic medical condition that is characterized by the sudden, involuntary and sometimes uncomfortable need to urinate any time during the day or night. OAB occurs when the bladder's smooth muscle squeezes while the bladder is still filling instead of when it is completely full, sending a signal to the brain that results in the urge to urinate. The condition is associated with poor quality of life that may result in significant social, psychological, occupational, domestic and physical stigmas. It is estimated that 12 to 18% of Canadians suffer from OAB.



Press Release

About Vesicare®

Vesicare® (Solifenacin Succinate) is a once-daily oral medication and is indicated for the treatment of overactive bladder in adults with symptoms of urinary urgency, urge urinary incontinence, and urinary frequency. It is not indicated for the management of stress incontinence, which can occur when the bladder leaks urine during exercise, coughing, or sneezing.¹ Vesicare has high affinity for muscarinic receptors in the bladder, which control the detrusor muscle and cause it to relax. This allows the bladder to fill normally and reduces the sense of urgency that a patient feels. In clinical studies, the most common side effects reported with Vesicare were dry mouth and constipation. Patients may also experience dry eyes, urinary retention, and blurred vision. Vesicare was approved by Health Canada in February 2006.

About Astellas Pharma Canada, Inc.

Astellas Pharma Canada, Inc. is highly focused on customers and their needs and is committed to making a difference in urology. The company also seeks to develop breakthrough products in infectious disease, immunology, dermatology and cardiovascular disease. Astellas Pharma Canada, Inc. is one of the Astellas Group of companies in North America and an affiliate of Astellas Pharma Inc., located in Tokyo. The organization is committed to becoming a global category leader by combining outstanding research and development and marketing capabilities. Additional corporate information is available at www.astellas.com/ca.

For more information and to book interviews contact:

Communications MECA

416-425-9143 or 1-866-337-3362