Toviaz 8 Mg Was More Effective Than Detrol LA In Treating Urge Urinary Incontinence In Patients With Overactive Bladder

Wednesday, December 16, 2009 - 06:31am

First Head-to-Head Trial Designed to Compare Toviaz 8 mg with Detrol LA 4 mg

(BUSINESS WIRE)--Patients treated with Toviaz® (fesoterodine fumarate) 8 mg extended release tablets had greater and statistically significant reductions in urge urinary incontinence episodes at week 12 (P=0.017) compared with Detrol® LA (tolterodine tartrate extended release capsules) in a placebo-controlled randomized clinical trial. The primary endpoint of the study was reductions in urge urinary incontinence episodes. This new study, published today in the January issue of BJU International, is the first head-to-head superiority trial specifically designed to compare the two medications.

When looking at prespecified secondary endpoints, patients treated with Toviaz 8 mg had a significantly greater increase in the average volume of urine voided per micturition from baseline to week 12 compared with those who received Detrol LA (P=0.005). The differences between Toviaz 8 mg and Detrol LA in urinary frequency (P=0.380) and urgency episodes (P=0.054) were not statistically significant.

“This is the first clinical trial that has been designed to assess the superiority of an antimuscarinic agent for the treatment of overactive bladder. This new data provides important information to physicians making treatment decisions for patients with overactive bladder since it compares two available medicines. This study showed that Toviaz 8 mg was significantly more efficacious than Detrol LA in treating urge urinary incontinence,” said lead author Dr. Sender Herschorn, Sunnybrook Health Sciences Centre, Toronto.

About the Study

Of the 1,712 patients enrolled in this 12-week, randomized, double-blinded, placebo-controlled superiority study, 1,697 were randomized to receive either Toviaz 8 mg (n=679), Detrol LA 4 mg (n=684) or placebo (n=334) once daily for 12 weeks. All patients in the Toviaz group started on Toviaz 4 mg for one week, followed by Toviaz 8 mg for 11 weeks.

The most frequently reported adverse events were dry mouth (28 percent in the Toviaz 8 mg group, 16 percent in the Detrol LA group and 6 percent in the placebo group), headache (6 percent in the Toviaz 8 mg group, 3 percent in the Detrol LA group and 2 percent in the placebo group), and constipation (5 percent in the Toviaz 8 mg group, 4 percent in the Detrol LA group and 3 percent in the placebo group). Discontinuations due to treatment-related adverse events were 2 percent in the placebo group, 4 percent in the Detrol LA group and 6 percent in the Toviaz group.

After the study was completed, additional analyses (post hoc analyses) were done. In one post hoc analysis, patients in the study who were treated with Toviaz 8 mg showed statistically significant improvements over those treated with Detrol LA (P=0.015) as assessed by the three-day diary dry rate at week 12. Toviaz 8 mg also produced significantly greater improvements compared with Detrol LA as measured by the Patient Perception of Bladder Condition (P<0.001) and Urgency Perception Scale (P=0.014)at week 12.

Also in a post hoc analysis, patients in the study who were treated with Toviaz 8 mg showed significantly greater improvements over those treated with Detrol LA on all sections except one of the Overactive Bladder questionnaire, a questionnaire which assesses the bothersomeness of symptoms and health-related quality of life. At week 12, significant improvements were found in: Symptom Bother (P<0.001) and total health-related quality of life (P=0.006) as well as the Concern (P=0.008), Coping (P=0.002) and Social Interaction (P=0.019) sections of the questionnaire; improvements in the Sleep section (P=0.081) were not significant.

The results of a second head-to-head clinical trial with identical study design confirm the superiority of Toviaz 8 mg over Detrol LA 4 mg on the primary endpoint, urge urinary incontinence at week 12. As with this first trial, the results are planned to be submitted in 2010 for publication.

About Toviaz

Toviaz is an FDA-approved, once-daily prescription treatment for patients with symptoms of overactive bladder. Affecting an estimated one in six people, overactive bladder symptoms include frequent and sudden urges to urinate and wetting accidents. Toviaz comes with the YourWay™ plan (www.ToviazYourWay.com), a simple program designed to help educate patients about their condition and treatment expectations, and to encourage and empower patients to become more engaged in their treatment.

The recommended starting dose of Toviaz is 4 mg once daily. Based upon individual response and tolerability, the dose may be increased to 8 mg once daily. The ability to titrate the dose of Toviaz allows physicians to customize treatment for each patient based on individual history and need. Toviaz is not recommended for patients with severe hepatic impairment.

Doses greater than 4 mg are not recommended in patients with severe renal insufficiency or in patients taking a potent CYP3A4 inhibitor; in patients taking a weak or moderate CYP3A4 inhibitor, careful assessment at 4 mg is advised prior to increasing to 8 mg.

Important Information for Toviaz

If patients have certain stomach problems, glaucoma, or cannot empty their bladder, they should not take Toviaz.

Medicines like Toviaz can cause blurred vision, drowsiness, and decreased sweating. Patients should use caution when driving, doing unsafe tasks, or in especially hot environments, until they know how Toviaz affects them. Drinking alcohol while taking medicines such as Toviaz may cause increased drowsiness.

The most common side effects are dry mouth and constipation.

Toviaz treats the symptoms of overactive bladder (leaks, strong sudden urges to go, going too often).

Toviaz has benefits and risks. There may be other options.

Important Information for Detrol LA

Patients should not take Detrol LA if they have certain types of stomach problems, glaucoma, or cannot empty their bladder. The most common side effect is dry mouth. Other side effects may include headache, constipation, and abdominal pain.

Detrol LA treats the symptoms of overactive bladder (leaks, strong sudden urges to go, going too often). The recommended dose of Detrol LA is 4 mg daily. For patients with significantly reduced hepatic function or renal function or who are currently taking drugs that are potent inhibitors of CYP3A4, the recommended dose of Detrol LA is 2 mg daily.

Detrol LA has benefits and risks. There may be other options.

Please visit www.Toviaz.com or www.DetrolLA.com for full prescribing and patient information.

About BJU International

Established in 1929, BJU International is published 23 times a year by Wiley-Blackwell and edited by Professor John Fitzpatrick from Mater Misericordiae University Hospital and University College Dublin, Ireland. It provides its international readership with invaluable practical information on all aspects of urology, including original and investigative articles and illustrated surgery. www.bjui.org

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com

PfizerMedia:MacKay Jimeson, 212-733-2324orInvestors:Jennifer M. Davis, 212-733-0717