Study Shows Higher Dose Of Toviaz® (fesoterodine fumarate) Offers Greater Efficacy In Reducing Urge Urinary Incontinence In Patients With Overactive Bladder

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that a Phase 4 study assessing the efficacy and safety of Toviaz® (fesoterodine fumarate) 8 mg once daily in patients with overactive bladder (OAB) compared to Toviaz 4 mg once daily or placebo met its primary endpoint. The primary endpoint was change in mean number of urge urinary incontinence episodes per 24 hours from baseline to week 12. Toviaz 8 mg reduced urge urinary incontinence in patients with OAB statistically significantly more than Toviaz 4 mg. The efficacy of both doses was statistically significant versus placebo. The recommended starting dose of Toviaz is 4 mg once daily.

The safety and tolerability profile of both Toviaz doses in this study were consistent with previous studies. Adverse events occurred more frequently among subjects receiving the 8 mg dose of Toviaz than the 4 mg dose, and both doses of Toviaz had adverse event rates greater than placebo. The most common treatment-emergent adverse events were dry mouth, constipation and urinary tract infection.

"We are aware of no other approved overactive bladder medication that has demonstrated statistically superior efficacy of its higher dose versus lower dose in reducing urge urinary incontinence in a randomized controlled prospective study," said Steven J. Romano, M.D., senior vice president and medicines development group head, Primary Care Business Unit, Pfizer Inc. "This study further confirmed the efficacy of Toviaz 4 mg and the results show that Toviaz 8 mg can further reduce symptoms in patients who require additional efficacy beyond the 4 mg dose."

Urge urinary incontinence is the involuntary leakage of any amount of urine, associated with or immediately preceded by a sense of urgency. Approximately 455 million adults worldwide, including 33 million American adults, are estimated to suffer from OAB symptoms.

Study Background

The 12-week, randomized, double-blind, placebo-controlled, parallel-group study assessed the efficacy of Toviaz 8 mg compared to Toviaz 4 mg in reducing urge urinary incontinence in subjects with OAB after 12 weeks of treatment. Based on a screening diary, all study participants who met all entry criteria started on placebo. After two weeks, 1,955 subjects who received at least one dose of double-blind study drug were randomized in a 2:2:1 ratio to either receive Toviaz 8 mg (779 subjects), Toviaz 4 mg (790 subjects) or placebo (386 subjects). Subjects randomized to receive Toviaz 8 mg had their doses titrated, starting on Toviaz 4 mg for the first week, followed by Toviaz 8 mg for the remaining 11 weeks of the trial. No further dose adjustments were permitted for the remaining 11 weeks of the study. The subjects were instructed to take the study drug once every day in the morning.

The study was conducted at 246 sites in 27 countries. Further analyses will be conducted and a publication of the comprehensive results is planned at a later date.

Overactive bladder is a treatable medical condition often caused by involuntary contractions or spasms of the bladder muscle. Overactive bladder symptoms of urgency, frequency or urge urinary incontinence can be bothersome and can have a significant impact on important aspects of people's lives. Despite its prevalence, OAB is often unrecognized and untreated.

About Toviaz

The recommended starting dose for Toviaz is 4 mg once daily. Based upon individual response and tolerability, the dose may be increased to 8 mg once daily. Toviaz should

be swallowed whole; tablets should not be chewed, divided or crushed.

INDICATION

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

IMPORTANT SAFETY INFORMATION

If you have certain stomach problems, glaucoma, or cannot empty your bladder, you should not take Toviaz.

Toviaz may cause allergic reactions that may be serious. If you experience swelling of the face, lips, throat, or tongue, stop taking Toviaz and get emergency medical help right away.

Medicines like Toviaz can cause blurred vision, dizziness, drowsiness, and decreased sweating. Do not drive, operate machinery, or do unsafe tasks until you know how Toviaz affects you. Use caution in hot environments. Drinking alcohol while taking medicines such as Toviaz may cause increased drowsiness.

The most common side effects are dry mouth and constipation. Toviaz has benefits and risks. There may be other options. To learn more about Toviaz, please see the Full Prescribing and Patient Information.

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around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us.

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