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Study Shows Toviaz Is Effective In Reducing Urge Urinary Incontinence In Patients With Overactive Bladder After Suboptimal Response To Detrol LA

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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) in patients with overactive bladder (OAB) met its primary endpoint. Toviaz reduced urge urinary incontinence (UUI) in patients with OAB who had a suboptimal response (less than 50 percent reduction in UUI) to Detrol LA (tolterodine tartrate extended release), a commonly-prescribed treatment for the condition. UUI is the involuntary leakage of any amount of urine, associated with or immediately preceded by a sense of urgency.

The 14-week randomized, parallel group, placebo-controlled, double-blind multicentre study assessed Toviaz 8 mg in patients with OAB who had been taking Detrol LA 4 mg for two weeks and had less than 50 percent reduction in urge urinary incontinence episodes. After open-label treatment with Detrol LA 4 mg, treatment with Toviaz 4 mg was started for one week, followed by treatment with Toviaz 8 mg.

The study demonstrated that Toviaz 4 mg for one week followed by Toviaz 8 mg statistically significantly reduced the average number of urge urinary incontinence episodes (-2.37 episodes from baseline) per 24 hours ($p<0.0001$) in OAB patients who had a suboptimal response to Detrol LA 4 mg. The safety and tolerability profiles of fesoterodine and tolterodine were consistent with previous studies. The most common treatment-emergent adverse events for both fesoterodine and tolterodine were dry mouth and constipation. Further analyses will be conducted and a publication of the comprehensive results is planned at a later date.

“This study adds to the body of evidence supporting Toviaz as an effective treatment for patients with overactive bladder, including patients who may not have responded to Detrol LA,” said study principal investigator Dr. Steven A. Kaplan, professor of urology, Weill Cornell Medical College and director of the Iris Cantor Men’s Health Center at New York Presbyterian/Weill Cornell Medical Center in New York. “Health care professionals often question how to treat patients who have had a suboptimal response to Detrol LA, which is commonly used but does not have a dose higher than 4 mg, and these data may help to guide treatment decisions.”

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. Approximately 33 million American adults are estimated to suffer from OAB symptoms. Despite its prevalence, overactive bladder is often unrecognized and untreated.

Study Background

Based on a screening diary, subjects who met all entry criteria started open-label treatment with once-daily tolterodine 4 mg for two weeks. At the end of the tolterodine treatment period, subjects who had less than 50 percent reduction of mean urge urinary incontinence per 24 hours from the screening diary to the baseline diary were randomized to one of two treatment arms in a 1:1 ratio (fesoterodine 8 mg or placebo). The study treatment started with 4 mg/day of fesoterodine or matching placebo for one week; after one week of treatment, the dose increased to 8 mg/day of fesoterodine. 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 trial was conducted worldwide at 156 sites in 15 countries. A total of 2217 subjects were screened, of which 642 were randomized (322 fesoterodine 8 mg, 320 placebo).

About Toviaz

INDICATION

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

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.

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, drowsiness, and decreased sweating. Use caution when driving, doing unsafe tasks, or in especially hot environments, until you know how Toviaz affects you. 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.

About Detrol LA

INDICATION

Detrol®LA (tolterodine tartrate extended release capsules) 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 have trouble emptying your bladder, you should not take Detrol LA.

Detrol LA may cause allergic reactions that may be serious. Symptoms of a serious allergic reaction may include swelling of the face, lips, throat, or tongue. If you experience these symptoms, you should stop taking Detrol LA and get emergency medical help right away.

Medicines like Detrol LA can cause blurred vision, dizziness, or drowsiness. Use caution while driving or doing other dangerous activities until you know how Detrol LA affects you.

The most common side effects with Detrol LA are dry mouth, constipation, headache, stomach pain.

Detrol LA has both benefits and risks. There may be other options. Ask your doctor if Detrol LA is right for you.

To learn more about Detrol LA, please see Full Prescribing and Patient Information.

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