Pfizer’s Toviaz Shows Positive Top-Line Primary Endpoint Result In Study Of Overactive Bladder In Vulnerable Elderly Patients

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today the top-line primary endpoint result for Toviaz (fesoterodine fumarate) Study A0221049 – Efficacy and Safety of Fesoterodine Flexible Dose Regimen in Vulnerable Elderly Patients with Overactive Bladder. The study met its primary endpoint: treatment with Toviaz was found to be statistically significantly superior to placebo in reducing the mean number of urgency urinary incontinence (UUI) episodes per day at the end of treatment. 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. Approximately 33 million American adults are estimated to suffer from overactive bladder symptoms. Despite its prevalence, overactive bladder is often unrecognized and untreated. While the prevalence of overactive bladder increases with age, limited research has been conducted in older individuals with this condition.

“For older individuals with overactive bladder, incontinence accompanied by urgency is the symptom that is most bothersome and embarrassing, and greatly impacts their overall quality of life,” said Steven J. Romano, M.D., senior vice president, Head,

Medicines Development Group, Global Primary Care Business Unit, Pfizer Inc. “Importantly, this was the first study of any antimuscarinic agent to demonstrate efficacy and safety in the rapidly growing population of medically vulnerable seniors who struggle with overactive bladder.”

Study A0221049 was a randomized, double-blind, placebo-controlled, parallel-group, multicenter trial to compare the efficacy and safety of a flexible dose regimen of fesoterodine to placebo in vulnerable elderly subjects with overactive bladder symptoms of urinary urgency incontinence. Vulnerability was determined using the VES-13, a validated 13-item questionnaire assessing physical activity and activities of daily living, which predicts significant deterioration in health in older persons.

The 12-week trial enrolled 562 individuals aged 65 or older, with a mean age of 75, at 109 sites in the United States. After an initial 2-week screening period, subjects were randomized either to a fesoterodine 4 mg arm (281 subjects) or to placebo (281 subjects). After 4 weeks of treatment, subjects in the fesoterodine arm were permitted to increase their daily dose of fesoterodine to 8 mg per day, if desired; if subjects subsequently wished to be titrated back down to 4 mg/day of fesoterodine, they were permitted to do so. The primary endpoint was the change in mean number of UUI episodes per day at week 12 relative to baseline versus placebo.

No significant new safety concerns were identified in this medically complex, older study population. The most common adverse events were dry mouth and constipation.

About Toviaz

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, 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.

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