Toviaz Top-Line Primary Endpoint Results Positive In Overactive Bladder Study Of Nocturnal Urinary Urgency

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today top-line results for Toviaz (fesoterodine fumarate) Study A0221048 – Effectiveness and Safety of a Flexible Dose Regimen for Patients with Overactive Bladder including Nocturnal Urinary Urgency. The study met its primary endpoint, as treatment with Toviaz was found to be statistically significantly superior to placebo in reducing the mean number of urinary urgency episodes overnight during sleep hours after 12 weeks of treatment. Further analyses will be conducted on the initial data, including submission for publication of comprehensive results at a later date.

Overactive bladder is a treatable medical condition 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 Americans are estimated to suffer from overactive bladder symptoms. Despite its prevalence, overactive bladder is often unrecognized and untreated.

“Many patients with overactive bladder experience frequent interruptions during sleep hours from urinary urgency, which can be very disruptive and bothersome. In this study, Toviaz demonstrated efficacy in reducing the number of nocturnal urgency episodes,” said Steven J. Romano, M.D., senior vice president, Head, Medicines Development Group,

Global Primary Care Business Unit, Pfizer Inc.

Study A0221048 was a randomized, double-blind, double-dummy, placebo-controlled, parallel-group, multicenter trial to compare the efficacy and safety of a flexible dose regimen of fesoterodine to placebo in subjects with symptoms of overactive bladder, including nocturnal urinary urgency. The 12-week trial evaluated a total of 937 individuals at 108 sites in the U.S. After an initial 2-week period during which subjects received placebo treatment, subjects were randomized either to a fesoterodine 4 mg arm (463 subjects) or to placebo (474 subjects) if they had less than or equal to a 35% reduction in nocturnal urgency episodes. After 4 weeks of treatment, based on patient self-reporting, investigators could increase the daily dose of fesoterodine to 8 mg per day. The primary endpoint was change in mean number of nocturnal urinary urgency episodes per day at Week 12 relative to baseline. No significant safety concerns were identified, and the most common adverse events were dry mouth and constipation.

About Toviaz®

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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Pfizer Inc. MacKay Jimeson (media), 212-733-2324 or Suzanne Harnett (investors), 212-733-8009