Pfizer's TOVIAZ(TM) (fesoterodine fumarate) Receives FDA Approval for the Treatment of Overactive Bladder

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New Once-Daily Treatment from Market Leader Shows Significant Efficacy over 24 Hours
Many People with Incontinence Conditions Suffer without Seeking Medical Help, Recent NIH Report Shows

(BUSINESS WIRE)--Pfizer Inc said today that the U.S. Food and Drug Administration (FDA) approved TOVIAZ™ (fesoterodine fumarate) extended release tablets for the treatment of overactive bladder (OAB) symptoms. New once-daily TOVIAZ can significantly reduce the number of urge urinary incontinence episodes and the frequency of urination over 24 hours, symptoms of OAB that can significantly impact patients' lives. Overactive bladder is a bothersome medical condition that affects an estimated one in six Americans, yet still remains highly undertreated. TOVIAZ is currently available in Europe.

Structurally related to the most prescribed OAB medication, Pfizer's Detrol® LA (tolterodine tartrate extended release capsules), TOVIAZ can help regulate the involuntary contractions of the bladder associated with OAB. These contractions cause frequent, sudden urges to urinate. The two efficacious and well-tolerated doses of TOVIAZ, 4 mg and 8 mg, allow dosing flexibility to optimize treatment based on the individual patient response and tolerability.

"The emotional and social implications for people who suffer from OAB are challenging, yet the condition remains underdiagnosed and highly undertreated," said Nancy Muller, executive director, National Association For Continence. "We need to encourage people with OAB symptoms to stop simply coping and start talking to their doctors about finding

treatment approaches that work for them. New treatments, like TOVIAZ, offer healthcare professionals another option to help their patients."

Symptoms of OAB can have a profound effect on workplace productivity, social and sexual activity and sleep. Overactive bladder may also lead to other health problems, such as falls and fractures, urinary tract infections and skin disorders, sleep problems and depression. Despite the impact of OAB on patients' lives, research, including a March 2008 National Institutes of Health (NIH) report, concludes that the embarrassment and stigma associated with incontinence can cause sufferers to try to hide the condition from families, friends and even their doctors. As a result, many with incontinence conditions suffer without seeking help.

"Pfizer is proud to offer TOVIAZ, a new treatment for OAB symptoms that builds on our strong heritage in urology," said Jim Maffezzoli, senior director, group leader, Pfizer. "We will continue to partner with physicians and patients to provide extensive support and education to help enhance treatment success."

Dr. Victor Nitti, professor and vice chairman of urology at the New York University Langone Medical Center and a principal investigator for TOVIAZ, added, "The FDA approval of TOVIAZ is good news for patients and treating physicians. Clinical trials with TOVIAZ showed strong efficacy and favorable tolerability, and the ability to titrate the dose of TOVIAZ allows physicians flexibility in treating each patient based on individual history and need."

TOVIAZ Data Demonstrate Efficacy, Safety

The approval of TOVIAZ is based on two large 12-week Phase III clinical studies of 1,964 OAB patients. In these studies, patients showed up to an 88 percent median reduction in urge urinary incontinence with TOVIAZ 8 mg versus 50 percent with placebo. Treatment with TOVIAZ 8 mg reduced the number of urinations per day by up to 19 percent compared to an 11 percent reduction with placebo treatment. Reductions in wetting accidents with TOVIAZ were seen as early as week two of treatment and maintained over 12 weeks.

In clinical studies, the most commonly reported adverse event was dry mouth (incidence of 7 percent for placebo; 19 percent for TOVIAZ 4 mg; 35 percent for TOVIAZ 8 mg). Most cases of dry mouth were mild to moderate with less than one percent of patients discontinuing TOVIAZ due to dry mouth. There was a low incidence of constipation (2 percent with placebo; 4 percent with 4 mg; 6 percent with 8 mg). TOVIAZ was evaluated for up to three years in open-label studies, with an adverse event profile similar to that

seen in previous trials.

TOVIAZ will be available in the United States in the first half of 2009.

Important Safety Information for TOVIAZ and Detrol LA

TOVIAZ and DETROL LA treat the symptoms of overactive bladder (leaks, strong sudden urges to go, going too often).

If you have certain stomach problems, glaucoma, or trouble getting urine to pass, you shouldn’t take TOVIAZ or DETROL LA.

The most common side effects (≥4%) of TOVIAZ are dry mouth and constipation.

The most common side effects (≥4%) of DETROL LA are dry mouth, headache, constipation, and abdominal pain.

TOVIAZ and DETROL LA, like all medicines, have benefits and risks. There may be other options. Ask your doctor if TOVIAZ or DETROL LA is right for you. For more information, visit TOVIAZ.com. or DETROLLA.com.

About Overactive Bladder

Overactive bladder is a treatable medical condition defined by urinary urgency (a sudden compelling desire to pass urine that is difficult to defer) with or without urgency urinary incontinence (the involuntary leakage of any amount of urine, associated with or immediately preceded by urgency), increased daytime urinary frequency and nocturia.

Overactive bladder affects an estimated one in six Americans; yet it is not necessarily a natural part of aging as many people assume. Overactive bladder can impact a wide range of health-related quality of life issues. However, many people with OAB do not seek medical help due to embarrassment or the belief that nothing can be done to alleviate their symptoms.

Please visit www.TOVIAZ.com for full prescribing and patient information.

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