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**FDA Approves Vesicare® (solifenacin succinate) for the
Treatment of Overactive Bladder**

–New Once-Daily Product Reduces Incontinence Episodes in Patients with OAB–

Paramus, NJ and Research Triangle Park, NC (November 22, 2004) - Vesicare® (solifenacin succinate) has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of overactive bladder (OAB) with symptoms of urgency, frequency, and urge incontinence. In clinical studies, Vesicare 5 mg and 10 mg showed clinical and statistical improvements in all symptoms of OAB. Specifically, once-daily Vesicare was found to significantly reduce the number of incontinence episodes for patients during a 12-week study period.

OAB is a medical condition that causes the bladder muscle (known as the detrusor muscle) to contract while the bladder is filling with urine, rather than when the bladder is full. Patients with OAB feel the urge to urinate more often, without advance warning, and when the bladder isn't completely full. This results in a patient experiencing urgency (an immediate and strong sense to urinate), frequency (the need to frequently go to the bathroom), and for many, urge incontinence (an involuntary loss of urine).

“A key concern for OAB patients is the very real fear of having an accident in public,” said, Peter Sand, MD, Director of Urogynecology, Northwestern University. “The approval of Vesicare is important because it offers patients a treatment with a favorable safety profile that reduces symptoms—in particular the chance of accidental leaks.”

While OAB affects an estimated 17-20 million men and women in the United States, few understand that it is a treatable condition. Many mistakenly believe this is a natural part of aging, are embarrassed to discuss it, or believe there is no treatment option available.

Therefore, patients gradually develop coping behaviors to manage their symptoms. These coping mechanisms include restricting fluids, carrying extra clothing, “mapping” bathroom locations, or even choosing not to leave the house. None of these behaviors, however, are clinically proven to be successful in treating the symptoms of OAB.

The debilitating effects of OAB exact not only a physical, social, and emotional toll on patients, but a financial one as well. It is estimated that costs related to OAB were nearly \$14 billion in the United States in 2000, similar to that of gynecological and breast cancers, osteoporosis, or arthritis.

Clinical Trial Results

The approval of Vesicare was based on clinical findings from 4 double-blind, 12-week, randomized, placebo-controlled, parallel-group, multicenter trials involving more than 3,000 patients with symptoms of urgency, frequency, and/or urge incontinence.

- Once-daily Vesicare 5 mg and 10 mg showed statistically and clinically significant improvement in all major symptoms of OAB.
- Reduction in the number of incontinence episodes was also significantly greater with Vesicare 5 mg and 10 mg ($p < 0.001$) compared to placebo.
- Vesicare has approximately a 50-hour half-life. Also, once-daily Vesicare demonstrated 24-hour control of OAB symptoms.
- Across all 4 studies, the efficacy of once-daily administration of 5 mg or 10 mg of Vesicare was consistent across patient age and gender.
- The most common side effects were dry mouth (5 mg 10.9%; 10 mg 27.6% vs. placebo 4.2%), constipation (5 mg 5.4%; 10 mg 13.4% vs. placebo 2.9%), and blurred vision (5 mg 3.8%; 10 mg 4.8% vs. placebo 1.8%).

About Vesicare®

Vesicare is indicated for the treatment of OAB with symptoms of urgency, frequency, and urge incontinence. The recommended dose of Vesicare is 5 mg once-daily. If the 5 mg dose is well tolerated, the dose may be increased to 10 mg once-daily. As with other anticholinergic agents, Vesicare is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, and in patients who have demonstrated hypersensitivity to the drug substance or other components of the product. Vesicare should be administered with caution to

patients with bladder outflow obstruction, decreased gastrointestinal motility, controlled narrow-angle glaucoma, and reduced renal or hepatic function.

For more information please visit www.vesicare.com (available by 5:00 pm Eastern, November 22, 2004).

Yamanouchi, GlaxoSmithKline Collaboration

In August 2003, Yamanouchi and GlaxoSmithKline signed an agreement for the co-promotion of Vesicare in the United States. Both companies are collaborating to help ensure an expeditious and efficient launch of Vesicare into the United States market and an opportunity to bring a new treatment option to the estimated 17-20 million people in the United States with OAB.

About Yamanouchi Pharmaceutical Co., Ltd.

Yamanouchi Pharmaceutical Co., Ltd., established in 1923, and headquartered in Tokyo, is a leading pharmaceutical company in Japan. With subsidiaries worldwide, Yamanouchi is expanding its business base to Europe, the United States, and Asia, and employs approximately 7,300 people. The company has discovered and developed many medicines now marketed in the United States through successful licensing agreements. For detailed company information, visit www.yamanouchi.com.

About GlaxoSmithKline

GlaxoSmithKline, one of the world's leading research-based pharmaceutical and healthcare companies, is committed to improving the quality of human life by enabling people to do more, feel better, and live longer. For more information, please visit the company's Web site at www.gsk.com.

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Contact Lisa Behrens at 919-483-2839 for full prescribing information.