GlaxoSmithKline today announced the approval of Requip® XL™ (ropinirole extended-release tablets) in the U.S. for the treatment of the signs and symptoms of idiopathic Parkinson’s disease. It is the first and only oral once-daily non-ergot dopamine agonist indicated for Parkinson’s disease. The product should be available in U.S. pharmacies in mid-July 2008.

Patients with Parkinson’s disease may experience what is commonly known as “off” time when their medication wears off and their symptoms return. Symptoms such as slowness of movement, tremor, and rigidity can be problematic for these patients, causing simple activities and movement to become difficult. Results from a pivotal efficacy and safety trial showed that adding extended-release ropinirole to patients’ existing levodopa (l-dopa) therapy reduced the amount of “off” time experienced by patients with Parkinson’s disease by 2.1 hours per day on average, compared to baseline. Specifically, comparing the experience of the group treated with extended-release ropinirole versus the placebo group, the adjusted mean difference in the reduction of “off” time was -1.7 hours, which was statistically significant.

“Many patients require multiple doses of one or more medications to control their Parkinson’s symptoms, which makes taking their medicines correctly and at the right times challenging. In addition, patients with Parkinson’s disease may have trouble completing routine activities of daily living and self-care,” said clinical investigator Rajesh Pahwa, M.D., professor of Neurology and director of the Parkinson’s Disease and Movement Disorder Center at the University of Kansas Medical Center in Kansas City. “Requip XL provides continuous delivery of ropinirole over 24 hours to provide smoother blood levels without the peaks and troughs that multiple daily doses typically deliver. It is an important once-daily treatment option for patients with Parkinson’s disease.”

Requip XL is an extended-release, once-daily tablet formulation that uses SkyePharma PLC’s (LSE: SKP) patented GEOMATRIX™ technology. This innovative tri-layer formulation allows for continuous delivery of ropinirole over 24 hours to provide smooth blood levels. Extended-release ropinirole offers physicians and patients a simple titration regimen; it also offers a convenient, once-daily dosing schedule compared to other oral dopamine agonists, which are dosed multiple times a day.

**Clinical study**

FDA approval was based primarily on results from the EASE-PD (Efficacy And Safety Evaluation in Parkinson Disease) Adjunct Study, a multi-center, double-blind, placebo-controlled study conducted in patients with idiopathic Parkinson’s disease not adequately controlled with l-dopa. A total of 393 patients in the study were randomized to receive either extended-release ropinirole (n=202) or placebo (n=191) once daily for 24 weeks in addition to l-dopa. The study’s primary endpoint was the mean change from baseline at week 24 in awake time spent “off”, which was measured via patient diaries. Results from the study showed that extended-release ropinirole significantly reduced “off” time by an average of 2.1 hours per day from baseline, compared to a reduction of 0.4 hours per day for placebo.

Once-daily use of extended-release ropinirole was generally well tolerated in the study. The withdrawal rate due to adverse reactions was low and similar between groups (6 percent extended-release ropinirole vs. 5 percent placebo). The most common adverse reactions reported in patients taking extended-release ropinirole compared to placebo were dyskinesia (13 percent vs. 3 percent), nausea (11 percent vs. 4 percent), dizziness (8 percent vs. 3 percent),
A progressively disabling disease
Parkinson's disease is a chronic, progressive, and often disabling neurological condition that eventually impairs the body's ability to move and balance. Researchers have determined that Parkinson's disease involves the degeneration of the cells in one of the brain areas responsible for motor control. Patients with Parkinson's disease experience a reduction in dopamine, a key chemical in the brain that communicates messages about movement, resulting in the symptoms of Parkinson's disease. These symptoms include tremor (involuntary shaking), rigidity (stiffness), akinesia (lack of movement or loss of spontaneous movement), bradykinesia (slower-than-normal voluntary movements), and problems with walking, balance and posture.

More than one million people in the United States have Parkinson's disease. The average age of onset of Parkinson's disease is about 60 years, but the disease can develop at an earlier age.

About Requip XL
Requip XL Tablets are indicated in the U.S. for the treatment of the signs and symptoms of idiopathic Parkinson's disease and are administered once daily. Prescription Requip XL is not for everyone. Requip XL may cause patients to fall asleep or feel very sleepy during normal activities such as driving; or to faint or feel dizzy, nauseated, or sweaty when they stand up. Patients should tell their doctor if they experience these effects or the following problems, or if they drink alcohol or are taking other medicines that make them drowsy. Side effects may include nausea, dizziness, drowsiness or sleepiness, headache, and sudden uncontrolled movements (dyskinesia). Increase or decrease in blood pressure and heart rate may occur. Hallucinations may occur at anytime during treatment. Patients should also tell their doctor if they experience new or increased gambling, sexual, or other intense urges while taking Requip XL. Requip XL may increase the side effects of l-dopa. Most patients were not bothered enough to stop taking Requip XL.

About SkyePharma PLC
Using its proprietary drug delivery technologies, SkyePharma develops new formulations of existing products to provide a clinical advantage and life-cycle extension. The company has 12 approved products in the areas of oral, inhalation, and topical delivery. The Group's products are marketed throughout the world by leading pharmaceutical companies. For more information, visit www.skyepharma.com.

About GlaxoSmithKline
Requip XL was developed and is marketed by GlaxoSmithKline, one of the world's leading research-based pharmaceutical and healthcare companies. More information on GlaxoSmithKline is available at the company's Web site at www.gsk.com.

Cautionary statement regarding forward-looking statements
Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2007.

For Full Prescribing Information for Requip XL in the U.S., please call +1 919 483 2839 or visit www.gsk.com.

Editor's Note: Requip XL is currently approved in Austria, Belgium, Czech Republic, Denmark,
Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, The Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, and United Kingdom.

Requip® XL™ will also be known as Requip® LP, Requip-Modutab®, and Requip® Depot in Europe.

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