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STUDY SHOWS REQUIP® (ropinirole HCl) TABLETS SIGNIFICANTLY IMPROVE SYMPTOMS OF MODERATE-TO-SEVERE PRIMARY RESTLESS LEGS SYNDROME

Results of a large study published in the January issue of *Mayo Clinic Proceedings*[1] provide significant evidence of the efficacy of **Requip**® (ropinirole HCl) in treating the symptoms of moderate-to-severe primary restless legs syndrome (RLS). Additionally, significant improvements in symptoms were observed after two nights of treatment. Identified in the early 1940s by neurologist Karl Ekbom, MD, RLS is characterized by: 1) An urge to move the legs, usually accompanied or caused by uncomfortable leg sensations; 2) Temporary relief with movement—partial or total relief from discomfort by walking or stretching; 3) Onset or worsening of symptoms at rest or inactivity, such as when lying or sitting; 4) Worsening or onset of symptoms in the evening or at night. RLS encompasses a range of severity that includes mild, moderate, and severe symptoms and affects approximately one in ten adults in the United States.

The "TREAT RLS US" (Therapy with Ropinirole, Efficacy and Tolerability in Restless Legs Syndrome) study was conducted to assess the efficacy, safety, and tolerability of the dopamine agonist ropinirole in the treatment of patients with moderate-to-severe primary RLS. The randomized, double-blind, placebo-controlled trial was conducted at 47 centers in the U.S. over 12 weeks. The study randomized 380 adult participants, and 331 (164 in the ropinirole group and 167 in the placebo group) completed the study.

Statistically significant differences favoring ropinirole versus placebo from baseline to week 12 ($p < 0.001$) occurred in the International Restless Legs Syndrome (IRLS) Rating Scale total score as well as for all secondary endpoints: mean change from baseline in IRLS total score at week 1, and the proportion of patients who were "much" or "very much" improved (based on the Clinical Global Impression Improvement Scale) at weeks 1 and 12 ($p < 0.001$).

With respect to the safety profile of ropinirole, overall, 82.9% (155/187) of the ropinirole participants and 66.8% (129/193) of the participants in the placebo group reported at least one adverse event during the study. Although most adverse events were mild or moderate, 17.6% of participants in the ropinirole group and 10.4% of the placebo group reported at least one severe adverse event (nausea and vomiting were the only severe adverse events experienced by more than 2% of participants). In this study, the most common adverse events reported in the ropinirole group (n=187) versus placebo (n=193) were nausea (43% versus 8%), headache (17% versus 19%), somnolence (13% versus 7%), and nasopharyngitis (11% versus 12%). The withdrawal rate due to adverse events was similar between the two groups (ropinirole 3% versus placebo 4%).

Important Safety Information About Requip®

Requip has been associated with sedating effects, including somnolence, and the possibility of falling asleep while engaged in activities of daily living, including operation of a motor vehicle. *Requip* should be discontinued if these events occur; it is unknown if dose reduction will eliminate episodes of somnolence. Prescribers should reassess patients for somnolence throughout treatment.

Syncope or symptomatic hypotension may occur, particularly during initial treatment or dose titration. Patients should be cautioned against rising rapidly after sitting or lying down. Because of possible additive effects, caution should be exercised with patients who have sleep disorders or are taking sedating medications, alcohol, CNS depressants, or medications that increase ropinirole plasma levels.

For full prescribing information for *Requip*, healthcare providers should visit www.Requip.com or call the GSK Customer Response Center at 1-888-825-5249.

Reference:

1. Bogan, R *et al*; Ropinirole in the Treatment of Patients with Restless Legs Syndrome: A US-based Randomized, Double-blind, Placebo-controlled Clinical Trial. Mayo Clin Proc 2006;81(1):17-27.