

## **ROTIGOTINE TRANSDERMAL PATCH IS EFFECTIVE IN THE TREATMENT OF IDIOPATHIC RLS: RESULTS OF A 6-MONTH, MULTICENTER, DOUBLE BLIND, PLACEBO-CONTROLLED TRIAL**

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### **Objective:**

To evaluate efficacy and safety of rotigotine transdermal patch in patients with moderate to severe idiopathic RLS.

### **Methods:**

Multicenter, randomized, double-blind, placebo-controlled, 5-arm parallel-group trial with 4 fixed doses of rotigotine 0.5-3mg/24h (2.5-15cm<sup>2</sup>). IRLS sum score and the CGI item I are the co-primary efficacy parameters.

### **Results:**

505 patients (52 ± 13 years, 61% female) were randomized at 58 sites in the US. The mean baselines scores were: IRLS 23.3±5.0 and CGI 4.7±0.7. For rotigotine at doses of 0.5, 1, 2, and 3mg/24h, improvement net effects versus placebo after 6 months treatment were -2.2±1.2, -2.3±1.2, -4.5±1.2(p<0.001), and -5.2±1.2(p<0.001) in the IRLS and -0.35±0.19, -0.32±0.19, -0.65±0.19(p<0.001) and -0.90±0.19(p<0.001) in CGI item I.

At least 1 adverse event was reported by 88 % of patients. Most common side effects were application site reaction (27.2%), nausea(21.5%), headache(17.6%) and somnolence(12.6%). AEs were usually mild to moderate in intensity and transient.

### **Conclusion:**

Therapy with rotigotine transdermal patch in doses of 2 and 3 mg/24h over a period of 6 months resulted in a statistically significant and clinically relevant reduction in the IRLS score and CGI item I compared to placebo and was well tolerated.