Background

• The development of motor complications in patients with Parkinson’s disease (PD) is associated with pulsatile stimulation of dopamine receptors, especially when using short-acting dopaminergic agents.1

• Pulsatile stimulation due to fluctuating plasma levels of orally administered dopamine agonists may limit the long-term effectiveness of these drugs.1,2

• Rotigotine® is a unique dopamine agonist with activity across D1 through D5 receptors as well as select adrenergic and serotoninergic sites;3 continuous, steady-transdermal delivery maintains stable plasma levels over 24 hours with a single daily application.1

• In a 6-month, randomized, double-blind, placebo-controlled trial, rotigotine was shown to be well tolerated and more effective than placebo in the treatment of early-stage PD.1,2

Objective

• To assess the long-term safety, tolerability, and efficacy of rotigotine transdermal system in subjects with idiopathic PD.

Methods

Study Design

• This was an open-label, long-term extension (SP702, ClinicalTrials.gov: NCT00594165) of the 6-month, double-blind study (Figure 1). Subjects completing the double-blind study had the option to enter long-term treatment with rotigotine in the open-label extension.

• Mean UPDRS (II+III) scores declined from an initial -5.6 point improvement to the double-blind baseline value in the first 2 years of open-label treatment, and remained within 4 points of the baseline value thereafter.

Safety

• There were no clinically relevant changes in vital signs or ECG findings.

Efficacy

• Mean UPDRS (II + III) scores declined from an initial -5.6 point improvement to the double-blind baseline value in the first 2 years of open-label treatment, and remained within 4 points of the baseline value thereafter.

Conclusions

• Rotigotine transdermal system was generally well tolerated by subjects with idiopathic PD for up to 6 years of treatment.

• Mean UPDRS (II + III) scores demonstrated sustained efficacy (scores still below baseline) of rotigotine over 2 years of open-label treatment, and remained within 4 points of the baseline value for a further 4 years.

References


