

# PD Outcomes No Better With Early Treatment

BY DAMIAN McNAMARA

MIAMI BEACH — The early treatment of people with Parkinson's disease with the dopamine receptor agonist pramipexole does not significantly modify the course of disease at 15 months, according to data from a phase I/II study.

"Pramipexole is an effective symptomatic drug for Parkinson's, but the findings from this study do not show that early treatment is disease modifying," Dr. Anthony Schapira reported at the World Federation of Neurology World Congress on Parkinson's Disease and Related Disorders.

Pramipexole (Mirapex) is approved by the Food and Drug Administration for the treatment of the signs and symptoms of idiopathic Parkinson's disease and for moderate-to-severe primary restless legs syndrome.

A total 261 patients were randomized to 6 to 9 months of pramipexole and comprised the early treatment

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group. Another 274 patients took a placebo during this phase, and then all of the patients took pramipexole up to 15 months.

The primary outcome of the PRamipexole On Underlying Disease (PROUD) Phase I/II study was the change in Unified Parkinson's Disease Rating Scale (UPDRS) total score at the end of 15 months compared with baseline scores.

The mean age in each group was 62 years, and the mean duration of Parkinson's disease at baseline was 1.8 years. Total UPDRS scores were based on parts I, II, and III of the instrument. Treated patients took the dopamine agonist only; no rescue drugs were allowed.

The dopamine agonist was dosed at 1.5 mg/day. "At this dose of pramipexole, there was no difference in UPDRS or imaging finding between early and late onset," Dr. Schapira said.

The difference in adjusted mean total score between groups was only 0.4 UPDRS units at 15 months, a nonsignificant finding.

"Early improvement was seen in the early [treatment] group, but then there was a decline. In the late group, [the patients] were initially worse but responded and ultimately ended up at the same point at 15 months," said Dr. Schapira, head of the department of clinical neurosciences at University College London.

Assessment of differences in UPDRS scores at 6 to 9 months and on the Parkinson's Disease Questionnaire (PDQ-39), a

39-item questionnaire that measures health status, were secondary outcomes.

These two measures were significantly different between early and delayed treatment groups—a 4.8 unit adjusted mean difference in UPDRS total score and improved PDQ-39 scores each favored early treatment with pramipexole over placebo.

In addition, a subset of 123 patients underwent single-photon emission computed tomography with the radiopharmaceutical agent DaTSCAN (<sup>123</sup>I-loflupane) to detect loss of nigrostriatal dopaminergic neurons.

"There were no differences in striatal DaTSCAN uptake," Dr. Schapira said. "About 15% showed uptake in both groups." ■

## VITALS

**Major Finding:** Patients with Parkinson's disease who received early treatment with pramipexole had a mean UPDRS score only 0.4 points different from patients who initiated treatment 6-9 months later.

**Data Source:** Phase I/II study on 535 patients with Parkinson's disease.

**Disclosures:** The study was sponsored by Boehringer Ingelheim. Dr. Schapira reported no relevant disclosures.

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