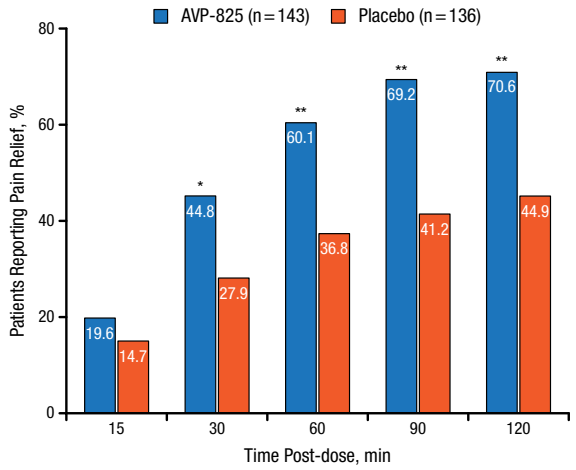
Figure 1. Comparison of Pain Relief With AVP-825 and Placebo



*P<.01; **P<.001.
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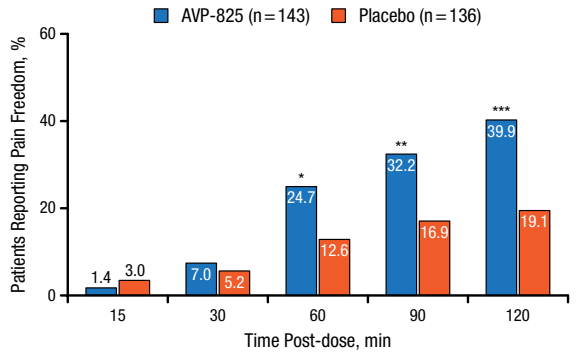
Figure 2. Comparison of Pain Freedom With AVP-825 and Placebo



*P<.05; **P<.01; ***P<.001.
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At 120 minutes, significantly more AVP-825–treated patients reported no clinical disability (P<.01), no migraine-associated symptoms (P<.05), and meaningful pain relief (P<.001). Additional rescue medication was less likely to be used during the first 48 hours by patients in the AVP-825 group. More AVP-825–treated patients reported TEAEs: 36% vs 11% for placebo. The most common TEAEs were abnormal taste, nasal discomfort, rhinorrhea, and rhinitis. There was a very low incidence of triptan sensations associated with AVP-825.

AVP-825 is a drug–device combination product containing low-dose (22 mg) sumatriptan delivered intranasally via a breath-powered device. As a treatment for migraines, it is well tolerated and delivers rapid headache relief that is sustained over placebo out to 48 hours.

MODERATO Study to Assess the Effect of Rasagiline on Patients With Parkinson Disease and Mild Cognitive Impairment

Written by Maria Vinall

Parkinson disease with mild cognitive impairment (PD-MCI) is thought to affect as many as one-third of nondemented PD patients. However, it is rarely diagnosed, and currently there are no approved treatments. The MODERATO study [NCT01723228] is designed to evaluate the effect of rasagiline on cognitive function in adult PD patients with MCI. Daniel Weintraub, MD, University of Pennsylvania and the Parkinson's Disease Center at the Philadelphia VA Medical Center, Philadelphia, Pennsylvania, USA, and one of the study investigators, presented the MODERATO study design and the baseline data for the enrolled patients.

Rasagiline is a selective irreversible MAO-B inhibitor indicated for the treatment of signs and symptoms of PD. Results of a small randomized, double-blind, placebo-controlled study indicated that it might exert beneficial effects on attention and executive abilities in PD patients with MCI [Hanagasi HA et al. *Mov Disord.* 2011].

MODERATO, the largest trial to date to evaluate a treatment for PD-MCI, is a 24-week, double-blind, placebo-controlled, phase 4 add-on study in men and women aged 45 through 80 years with idiopathic PD (based on the UK Parkinson's Disease Society Brain Bank Clinical Diagnostic Criteria) and PD-MCI as defined by the Movement Disorder Society Task Force Diagnostic Criteria and a Montreal Cognitive Assessment (MoCA) rating scale score of 20 to 25. Patients were required to be Hoehn and Yahr stage ≥1 and ≤3 and on a stable dopaminergic medication regimen for ≥30 days before entering the study. Patients with dementia were excluded. Eligible participants were randomized to 24 weeks of treatment with rasagiline 1 mg/d or placebo in addition to their current medications.

The purpose of the study is to measure the effectiveness of rasagiline on cognition in PD-MCI individuals with mild cognitive impairment. The primary study outcome measure is the mean change from baseline to week 24 in the Scales for Outcomes in Parkinson's Disease-Cognition summary score. Key secondary measures include the Unified Parkinson's Disease Rating Scale motor and activities of daily living scores, MoCA scores, and Functional Independence Index. A total of 170 patients have been enrolled from 40 study centers.