

FDA Approves Tavapadon for Parkinson's Disease: JAMA

The US FDA has approved tavapadon (Juvmo), an oral selective D1/D5 dopamine agonist, for the treatment of adults with Parkinson's disease.

Tavapadon was evaluated as monotherapy in early Parkinson's disease in the TEMPO-1 and TEMPO-2 trials, and as adjunctive therapy with oral levodopa in patients with advanced disease and motor fluctuations in the TEMPO-3 trial.

JUVMO Is a New Kind of Treatment for Parkinson's Disease

"The approval of JUVMO marks the first dopaminergic breakthrough for [Parkinson's disease](#) in decades," said Roopal Thakkar, M.D., executive vice president, research and development, chief scientific officer, AbbVie. "People living with Parkinson's and the clinicians who care for them have long faced difficult tradeoffs between motor control, treatment burden and tolerability. Clinicians now have a new treatment option that targets dopamine pathways differently and reduces the difficult tradeoffs associated with D2/D3 selective dopamine agonists."

Needed Innovation in the Parkinson's Disease Treatment Landscape

For people living with Parkinson's disease, maintaining consistent control of motor symptoms becomes increasingly challenging as the disease progresses. Oral levodopa remains the foundation of treatment and is often effective at controlling symptoms, but many patients require higher and more frequent doses over time. These adjustments can help restore symptom control yet may also contribute to treatment-related complications such as dyskinesia. About 70% of people living with Parkinson's disease have their oral levodopa dose increased within the first year of therapy.

These challenges highlight the need for new treatment approaches that can help address the evolving needs of people living with Parkinson's disease. After 85 weeks on JUVMO, 93% of clinical trial participants had not increased their oral levodopa dose and 94% of participants with early Parkinson's disease had not started oral levodopa.³

Dopamine agonists have long been used to help manage symptoms and reduce reliance on oral levodopa escalation. However, currently available dopamine agonists primarily target D2/D3 receptors and their use may be limited by tolerability concerns. JUVMO introduces a different approach, selectively targeting D1/D5 receptors to provide health care providers and patients with a new option for managing motor symptoms across the Parkinson's disease continuum.

Why the Approval of JUVMO Matters for People across the Spectrum of the Disease

"Parkinson's disease treatment has long required health care providers to balance the need for dependable motor symptom control with considerations around treatment tolerability," said Hubert Fernandez, M.D., professor of neurology at the Cleveland Clinic Lerner College of Medicine and global principal TEMPO trial investigator. "Now we have a novel therapy that selectively targets D1/D5 receptors, which addresses a longstanding need for innovation and provides health care providers with greater flexibility to tailor treatment to individual patient needs."

Perspective from the Parkinson's Community

"For people with Parkinson's and their families, progress means having treatment options that deliver meaningful benefit in everyday life," said Brian Fiske, PhD, chief scientist of The Michael J. Fox Foundation for Parkinson's Research. "Each therapy approval is an important milestone in building a diverse treatment pipeline needed to meet the full range of unmet needs across the Parkinson's community."

AbbVie expects to make JUVMO available to patients in the U.S. in October 2026.

FDA Approval Was Supported by Phase 3 TEMPO Clinical Trial Data

Phase 3 data from the TEMPO clinical trial program demonstrated the efficacy and safety of JUVMO in people with early Parkinson's disease who were not taking oral levodopa (TEMPO-1 and 2) and as an adjunct to oral levodopa in people with Parkinson's disease experiencing motor fluctuations (TEMPO-3).¹

- In TEMPO-1 at week 26, JUVMO significantly improved activities of daily living scores versus placebo, as measured by MDS-UPDRS Part II, which includes everyday tasks like dressing, eating and personal hygiene (placebo: +0.9; 5 mg: -1.6; 15 mg: -1.7; $p < 0.0001$ each dose versus placebo).
- Compared to baseline, JUVMO improved activities of daily living scores by 22-23% whereas the placebo group worsened by 12%.
- Additionally, JUVMO significantly improved activities of daily living and motor skills, as measured by MDS-UPDRS Part II + III combined scores, versus placebo (placebo: +1.8; 5 mg: -9.7; 15 mg: -10.2; $p < 0.0001$ each dose versus placebo) at week 26.
- JUVMO also significantly improved MDS-UPDRS Part II scores versus placebo in TEMPO-2 at week 26 (placebo: 0.0; 5-15 mg: -1.5; $p = 0.0007$).
- JUVMO also significantly improved MDS-UPDRS Part II + III combined scores versus placebo in TEMPO-2 at week 26 (placebo: -1.2; 5-15mg: -10.3; $p < 0.0001$).
- In TEMPO-3 at week 26, JUVMO 5-15 mg + oral levodopa significantly increased total daily "on" time without troublesome dyskinesia versus placebo + oral levodopa (1.7 hours versus 0.6 hours, $p < 0.0001$).
- Total daily "off" time decreased by 1.9 hours with JUVMO + oral levodopa, compared to a decrease of 0.9 hours with placebo + oral levodopa ($p = 0.0006$).

- Sustained efficacy was observed out to 85 weeks for those who continued in the open-label extension period (TEMPO-4).
- Of those on JUVMO + oral levodopa for 85 weeks, 93% did not increase their oral levodopa dose (96/103). Of those on JUVMO without levodopa, 94% did not initiate levodopa (257/273).
- The majority of treatment-emergent adverse events (TEAEs) were non-serious and mild or moderate in severity.
- The most common TEAEs for JUVMO without oral levodopa, reported in $\geq 5\%$ of patients, were nausea, headache, dizziness, fatigue, dysgeusia, vomiting, dry mouth and anxiety.
- For JUVMO + oral levodopa, the most common TEAEs, reported in $\geq 5\%$ of patients, were nausea, dyskinesia, dizziness, headache, hallucinations and orthostatic hypotension.

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