Transcript Details

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Sustained Antidepressant and Sleep Benefits With Adjunctive Seltorexant in MDD: Double-Blind and Long-Term Extension Data From the MD3001 Trial

Announcer:
Welcome to DataPulse from Psych Congress 2025 on ReachMD, this activity titled Sustained Antidepressant and Sleep Benefits with Adjunctive Seltorexant in Major Depressive Disorder—Double-Blind and Long-Term Extension Data from the MD-3001 Trial is provided by Total CME.

Dr. Thase:
Hello from Psych Congress 2025 here in San Diego. I'm Dr. Michael Thase, and today I'll review results from a phase 3 trial of adjunctive seltorexant. This will include both the double blind and 1-year open-label extension data in patients with major depressive disorder and insomnia symptoms. This particular study is known by the name MD-3001 and is one of a series of studies evaluating this treatment in patients with major depressive disorder.

I think this study is important because insomnia is one of the most common symptoms of depression. It's associated with both the level of disability and the global level of severity. And although we have many effective antidepressants, we don't have many antidepressants that are also good for the insomnia associated with depression. So what seltorexant is hoped to add is benefit for the insomnia that persists despite antidepressant treatment and then an additive extra benefit for the level of depression that patients taking standard antidepressants still experience.

So it's a simple study. It's 2 arms. One group gets active seltorexant 20 mg a day. The other group gets an identical placebo. Outcomes are evaluated without knowledge of which study group the patient comes from. And the primary outcome is the Montgomery-Åsberg Depression Rating Scale on day 43, essentially after 6 weeks of double-blind treatment. I think most importantly, the study succeeded on its primary endpoint. There was a significantly greater improvement on Montgomery-Åsberg scores on day 43 and that improvement persisted when the Montgomery-Åsberg was adjusted by removing the insomnia item. There was also a significant benefit on the PROMIS sleep disturbance scores.

I think equally important is that the safety profile overall for seltorexant was comparable to the safety profile of the placebo in this adjunctive therapy study. So this treatment benefit occurred without added side effect burden.

The open-label extension showed that the benefit persisted out over a year and, in fact, patients continued to improve. Those who got placebo in the initial phase, improved initially more than those who got active drug, simply because they had more room for improvement coming out of the placebo arm. Overall, at the end of a year of treatment, patients had improved an additional 11 points on their Montgomery-Åsberg, so quite a bit of additional improvement. Other good news here is that no new safety signal was observed.

I think the study succeeded and provides us really important new information about a potential adjunctive treatment that is well tolerated and very helpful for the insomnia associated with depression.

So from the 2025 Psych Congress, I'm Dr. Michael Thase and thank you for listening.

Announcer:
Thank you for listening to this DataPulse from Psych Congress 2025 on ReachMD. This activity is provided by Total CME. Thank you for listening.