FDA-approved nasal spray for severe depression can lead to remission

The FDA has approved an esketamine nasal spray for the treatment of depression cases that do not respond to other therapeutic approaches. Image credit: Koldunov/Getty Images.

- Major depressive disorder (MDD) is the most commonly diagnosed mental disorder globally.
- The amount of people with MDD continues to increase every year.
- The Food and Drug Administration (FDA) recently approved the nasal spray Spravato for the treatment of MDD in those who have not responded to at least two oral antidepressants.

Hundreds of millions of people around the world live with major depressive disorder (MDD), making it the most commonly diagnosed mental disorder with numbers increasingTrusted Source annually.

Past studies show that only about 30% of people with MDD achieve full remission from their symptoms after using one antidepressant medication, and 50% have no response with just one drug.

“Over the past 20 years, we’ve been losing the battle to depression with rates of depression nearly doubling in the [United States],” Gregory Mattingly, MD, principal investigator in clinical trials of the Midwest Research Group, and founding partner of St. Charles Psychiatric Associates, told Medical News Today.

“Major depression is one of the greatest health challenges in the U.S., as approximately 21 million adults have had at least one major depressive episode and approximately one-third are considered to have challenging-to-treat depression. This obviously has a dramatic impact not

only on the individual but also their friends and loved ones. Major depression has one of the highest economic burdens of any psychiatric disorder," he pointed out.

Mattingly has been involved with recent research and clinical trials regarding Spravato (esketamine) — a prescription nasal spray made by Johnson & Johnson (J&J) used to treat depression that had been originally approvedTrusted Source by the Food and Drug Administration (FDA) in 2019.

Now, the FDA has also approved Spravato for treating adults with MDD who have not responded to at least two oral antidepressants**.**

What is Spravato?

According to J&J, Spravato is an N-methyl-D-aspartate (NMDA) receptorTrusted Source antagonist that appears to work by acting on a pathway in the brain that affects glutamateTrusted Source — a neurotransmitter that helps sends signals between nerve cells in the spinal cord and brain that help regulate a person's mood.

NMDA receptors in the brain and other areas of the central nervous system are mainly responsible for cognitive skills learning and memory.

By influencing the NMDA receptors in the central nervous system, Spravato helps to improve depression symptoms.

How does Spravato treat major depression?

Spravator's recent FDA approval is based on findings from a multicenter clinical trial where Spravato alone demonstrated quick and superior improvement in participants' Montgomery-Asberg Depression Rating Scale (MADRS) total score versus placebo.

According to the American Psychological Association (APA), the MADRS measures depression severity in adults 18 years and older via a 7-point scale.

During analysis, researchers found that Spravato showed numerical improvements across all 10 MADRS categories by day 28 of treatment.

Additionally, by the fourth week of the study, 22.5% of participants taking 84 milligram (mg) doses of Spravato achieved MDD remission with an MADRS total score of less than or equal to 12, and 18.3% of those on 56 mg does achieved remission, compared to 7.6% of participants taking the placebo.

"When Johnson & Johnson started researching Spravato, there had been no new MOA in the mental health space for more than 30 years," Mattingly said.

"This approval gives patients and healthcare professionals the freedom to further personalize treatment plans and options to determine the best way to incorporate Spravato into their care — either alone or in conjunction with an oral antidepressant. I have heard firsthand from patients about the transformational impact that Spravato has had on their lives, and I want that opportunity for all appropriate patients who may benefit from this important treatment option."

– Gregory Mattingly, MD

Step in the right direction for treating depression

MNT spoke with Eric C. Alcera, MD, chief medical officer and vice president at Hackensack Meridian Health at Carrier Behavioral Health in New Jersey, about this recent FDA approval.

"This is a step in the right direction in addressing those who suffer from major depression disorders," Alcera, who was not involved in the Spravato trials, commented. "The FDA approval allows prescribers a new path in treating patients with a faster alternative than traditional treatments, which can often take weeks to provide relief for those suffering from depression."

"This is a game changer for those patients who don't respond to traditional treatments, leaving them at risk for worsening of symptoms and quality of life and — worst — suicide," he told us.

"Having new innovative therapies, like Spravato, offers hope to those who are suffering from treatment-resistant depression. The more innovative therapies researchers develop, the more hope can be given to those who need it the mos," said Alcera.

Like with any new medications, Alcera noted, longitudinal studies for safety are necessary to ensure efficacy and understanding the long-term impact these medications can have.

"The longer we can keep patients from having severe symptoms from reoccurring improves their overall prognosis over the course of their life," he added. "I'd be interested to see if other forms of Spravato other than intranasal are being developed to better tailor the treatment for those who cannot tolerate an intranasal form of medication."

More evidence for esketamine use in depression treatment

MNT also spoke with David Merrill, MD, PhD, a board-certified geriatric psychiatrist at Providence Saint John's Health Center in Santa Monica, CA, and Singleton Endowed Chair in Integrative Brain Health, about this study, who said this FDA approval was good news.

"Basically, we need more treatment options for depression that have evidence behind them that the treatments work," Merrill said. "Ketamine is a safe medication when used under appropriate professional supervision, so FDA approval will lead to a safer, more well-regulated control and use of this medication in clinical practice for patients with major depressive disorder."

"Given the reality that antidepressant medications only work for a portion of patients with major depression, and there's a significant amount of treatment-resistant depression, where patients aren't able to find any current treatment that works to treat their depression," he continued. "The field, patients, and families are in need of more treatment options with different mechanisms of action."

Merrill said there has been debate within the scientific and medical communities about the difference between esketamine versus ketamine, and whether esketamine is as effective as regular ketamine.

“Hopefully, this approval by the FDA shows that there is sufficient evidence for esketamine working that providers and patients and their families will be comfortable and more confident that in as little as 24 hours, patients will start getting relief from the esketamine treatment, and that relief can last to the duration study through 28 days of treatment that’s been studied here,” he added.

News Source:

https://www.medicalnewstoday.com/articles/fda-approved-nasal-spray-for-severe-depression-can-lead-to-remission#More-evidence-for-esketamine-use-in-depression-treatment