Psychedelic drug MDMA faces FDA panel in bid to become first-of-a-kind PTSD medication

June 4 2024, by Matthew Perrone

In this photo made with a long exposure, a man is silhouetted against lights reflected in the waters off Cape Neddick in Maine on Dec. 11, 2017. Federal health advisers are considering the first request to approve the mind-altering club drug MDMA as a treatment for PTSD. The advisers to the Food and Drug Administration are scheduled to vote on the drug's safety and effectiveness Tuesday, June 4, 2024, potentially setting the stage for federal approval later this

year. Credit: AP Photo/Robert F. Bukaty, File

Federal health advisers are weighing the first-of-a-kind approval of MDMA, the mind-altering club drug, as a treatment for PTSD—part of a decadeslong effort by psychedelic advocates to win medical acceptance for the drug's purported benefits.

The Food and Drug Administration convened a panel of outside experts Tuesday to review the latest research on the drug, which appears to show it can help relieve post-traumatic stress disorder when combined with talk therapy.

But FDA regulators have questions about the reliability of that data, as well as MDMA's safety risks, which include the potential for heart problems, injury and drug abuse.

The FDA panel will vote later Tuesday on whether to recommend the drug's use for PTSD, which could set the stage for federal approval later this summer, though the FDA isn't required to follow the group's recommendations.

MDMA, sometimes called ecstasy or molly, would become the first illegal psychedelic, if approved, to make the leap to mainstream medicine. The drug is the first in a series of psychedelics—including LSD and psilocybin—that are expected to come before the FDA in the next few years as part of renewed research and interest into their potential to address hard-to-treat conditions like depression, addiction and anxiety.

Currently, only antidepressants are FDA-approved for PTSD, which is closely linked to depression, anxiety and suicidal behavior. PTSD is also

more prevalent among women and veterans.

But the FDA's review of MDMA highlights the challenges of studying and assessing psychedelic drugs.

"This application is both consequential and complex," FDA reviewer Dr. Tiffany R. Farchione said at the beginning of Tuesday's meeting.

Because MDMA causes intense psychological experiences, almost all patients in two key studies of the drug were able to guess whether they had received the MDMA or a dummy pill. That's the opposite of the objectivity usually required for high-quality drug research, in which patients can't tell whether they've received the drug being tested.

"This makes it hard to know how much of the treatment effect is a true benefit and how much is due to expectation bias," Farchione said.

The FDA will ask its outside panel about that issue and several others, including uncertainty about how long the benefits of MDMA might last. About 25% of patients dropped out of a follow-up study designed to track long-term outcomes.

FDA regulators also have concerns about the drug's safety risks, including whether patients may injure themselves if they are still impaired by the drug's effects, which can last eight hours or more. MDMA is also associated with increased blood pressure.

Because of those risks, the FDA has proposed strict limits on how and where MDMA could be used if approved. Only specially certified doctors and therapists would be able to prescribe and administer the drug. Patients would have to be registered and tracked over time. Health professionals also would need to be available to measure patients' vital signs while taking the drug.

Representatives for drugmaker Lykos Therapeutics said Tuesday they agreed with such precautions and hoped that would hasten the drug's approval.

"It's clear that MDMA-assisted therapy would be a welcome addition to the currently available options," said Dr. Kelley O'Donnell, a New York University psychiatrist who helped conduct the MDMA studies. "I've seen firsthand how this treatment can be lifesaving for some."

Lykos is essentially a corporate spinoff of the nation's leading psychedelic advocacy group, the Multidisciplinary Association for Psychedelic Studies, or MAPS, which funded the studies. The group was founded in 1986 to promote the benefits of MDMA and other mind-altering drugs.

In the two pivotal studies, patients received MDMA as part of an intensive, four-month course of talk therapy lasting more than a dozen sessions, only three of which involved taking the drug. Following treatment, patients who received MDMA had significantly lower PTSD scores.

MDMA acts on two feel-good brain chemicals that are thought to improve talk therapy: serotonin and dopamine. Experts believe the drug helps patients confront past traumas by reducing fear and enhancing their connection and trust with therapists.

Citation: Psychedelic drug MDMA faces FDA panel in bid to become first-of-a-kind PTSD medication (2024, June 4) retrieved 22 June 2024 from https://medicalxpress.com/news/2024-06-psychedelic-drug-mdma-fda-panel.html