US health regulator rejects MDMA treatment for PTSD, for now

August 10 2024

Credit: Unsplash/CC0 Public Domain

US health regulators on Friday denied an application for treating post-traumatic stress disorder (PTSD) with the drug MDMA, commonly known as ecstasy, saying more investigation needed to be done.

The company that submitted the application, Lykos Therapeutics, said in a statement that the Food and Drug Administration (FDA) had requested an additional Phase 3 clinical trial to study MDMA's "safety and efficacy."

A panel of experts convened by the FDA to evaluate clinical data on MDMA had overwhelmingly voted in early June to say there was insufficient evidence to prove it was effective.

While unsurprising, the decision announced Friday represents a blow to advocates of the novel treatment.

"The FDA request for another study is deeply disappointing, not just for all those who dedicated their lives to this pioneering effort, but principally for the millions of Americans with PTSD... who have not seen any new treatment options in over two decades, said Lykos CEO Amy Emerson.

PTSD is a debilitating mental health condition that develops after a person experiences or is threatened by traumatic events such as death, combat or sexual assault.

It affects an estimated five percent of Americans in any given year.

Pharmaceutical treatment options for PTSD are so far limited to two antidepressants that require three months of dosing to take effect, and response rates to the medications have been found to be uneven.

MDMA—methylenedioxymethamphetamine—is a Schedule 1 drug under the Controlled Substances Act, and approving it for medical use would have represented a major shift.

California-based Lykos based its request for regulatory approval on two

clinical studies, each of which enrolled around 100 people, to evaluate MDMA used together with other psychological interventions such as talk therapy, against a placebo with talk therapy.

These two studies, published in the prestigious journal *Nature Medicine*, indicated MDMA was indeed both safe and highly effective at treating PTSD.

But nine out of 11 experts on the FDA panel said available data was not enough to show the treatment was effective, and 10 out of 11 said the benefits did not outweigh the risks.

In a briefing document put together ahead of the meeting, FDA staff raised concerns about Lykos's clinical trial methodology and criticized the company for not gathering sufficient side effect data.

The company said it will "work diligently in the coming months to address FDA's concerns and to take advantage of agency processes to resolve scientific disagreements."

"We intend to work tirelessly and use all available regulatory pathways to find a reasonable and expeditious path forward," Emerson added.

Citation: US health regulator rejects MDMA treatment for PTSD, for now (2024, August 10) retrieved 10 August 2024 from https://medicalxpress.com/news/2024-08-health-mdma-treatment-ptsd.html