FDA Grants Citizen Petition Request to Extend Open Public Hearing on MDMA-Assisted Psychotherapy for PTSD

SILVER SPRING, MD, UNITED STATES, June 3, 2024 /EINPresswire.com/ -- Psymposia, Inc is a 501(c)(3) research non-profit with a mission to educate the public on psychedelic science and harm reduction.

On June 4, the United States Food and Drug Administration's (FDA) Psychopharmacologic Drugs Advisory Committee will convene to assess Lykos Therapeutics' (formerly MAPS Public Benefit Corporation) new drug application (NDA) of MDMA-Assisted Psychotherapy for the treatment of post-traumatic stress disorder (PTSD). The committee will assess the intervention's overall benefit-risk profile, including the potential public health impact.

On May 28, the FDA announced that it extended the advisory committee meeting to accommodate additional oral presentations from the public. The open public hearing (OPH) is now scheduled for 2:00–3:45 pm ET. The entire meeting will be streamed live on YouTube.

The OPH was extended in response to a citizen petition submitted April 28, which requested additional time to accommodate critical perspectives, followed by a large number of requests to speak from the public. Two authors of the petition — Drs. Neşe Devenot and Brian Pace — are board members of Psymposia. Four of the petition's co-authors will be participating in the OPH.

The FDA did not engage with other allegations raised within the petition including the suppression of serious adverse events, systematic boundary violations, and inadequate trial designs.

Members of Psymposia submitted written comments to the committee. Dr. Neşe Devenot commented on the therapy cult dynamics of the sponsor; Dr. Brian Pace commented on the sponsor's pattern of utopian evangelism; and Russell Hausfeld commented on the sponsor's history of instrumentalization and exploitation of veterans.

In the FDA's response to the citizen petition, the agency did not address the substance of the petition's concerns. This corresponds to the orientation reflected in the agency's meeting materials, as described in STAT News on May 31: "The FDA didn't highlight concerns about data suppression in its pre-meeting documents, suggesting it's satisfied with the trial reporting." Despite this signal of confidence, other organizations are investigating these allegations. The

journal Psychopharmacology — which published Lykos' Phase 2 trial results — has confirmed that its editors are taking the omission of serious adverse events seriously.

While the FDA has yet to acknowledge these issues, the concerns expressed in the petition were discussed during the Institute for Clinical and Economic Review's (ICER) May 30th public meeting. ICER — a patient-advocacy organization that reviews new drug applications before approval — conducted this public meeting to review Lykos Therapeutics' MDMA-Assisted Psychotherapy application.

ICER gave Lykos' trials an "Insufficient" rating — its lowest possible score.

The citizen petition's concerns over Lykos' clinical trials were echoed throughout ICER's public meeting on May 30. In his closing statement, Dr. Austin Frakt — a research professor and Associate Director at the the Boston VA — said, "There is a real reputational risk for clinical trials in general when you see a clinical trial in particular not well done, for things that are controllable. And I would say perhaps on the table for the FDA is agency risk. I don't know if they consider that, but I would be worried about that if I were them."

Describing Lyko's clinical trials, Dr. Julie Ryers, an ICER voting member, said: "we have a trial that, in my view, is ethically challenged to the point that it makes me squeamish."

Jason Schwartz, an associate professor of Health Policy and Management at Yale School of Public Health, summarized the need to scrutinize Lykos' decisions: "While some of [these trial issues] can be contextualized in isolation, like blinding, it's hard for me to construct a story that gives me confidence that all of these issues have a reasonable explanation."

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