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FDA approval of first-in-class MDMA-assisted therapy for PTSD is unlikely in 2024

Market Event Summary

Matthew D. Litke, M.S. | June 2024

FDA advisory panel issues negative opinion of MDMA-assisted therapy for the treatment of PTSD

FDA approval unlikely in 2024

- In February 2024, the FDA granted priority review to Lykos Therapeutics' NDA for orally administered MDMA capsules, used in concert with psychotherapy, for PTSD, with a PDUFA target action date of August 11, 2024. MDMA-assisted therapy had shown positive results in two Phase 3 clinical trials (MAPP1, MAPP2), one assessing the treatment in severe PTSD patients and the other in moderate to severe PTSD patients. Both trials met primary clinical endpoints, demonstrating a significant reduction in CAPS-5 total score versus placebo with psychotherapy. Additionally, the drug improved patient functioning relative to placebo (a secondary endpoint), and many treated patients in both trials experienced remission.
- On June 4, 2024, the FDA's Psychopharmacologic Drugs Advisory Committee concluded that the benefits of MDMA do not outweigh its risk for the treatment of PTSD by a vote of 10 to 1. Panelists noted concerns regarding both the efficacy (e.g., likelihood of skewed results because many trial participants had taken illicit MDMA earlier; concerns regarding the evaluation of the durability of treatment effect) and safety of MDMA (e.g., lack of abuse-potential assessment). A lack of effective blinding among both subjects and providers in the late-phase trials in PTSD was also of concern. In March 2024, ICER highlighted similar concerns regarding the conduct of these trials.

CAPS-5: Clinician-Administered PTSD Scale for DSM-5; FDA: Food and Drug Administration; ICER: Institute for Clinical and Economic Review; MDMA: midomafetamine; NDA: New Drug Application; PDUFA: Prescription Drug User Fee Act; PTSD: post-traumatic stress disorder;

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Clarivate's takeaways

The panel's lack of support makes approval unlikely in the near future.

The advisory panel overwhelming rejected MDMA as a PTSD treatment, with 9 out of 11 panelists disagreeing that the available data show MDMA is effective in patients with PTSD, and 10 out of 11 panelists disagreeing that its benefits outweigh its risks. We expect the FDA to follow the panel's recommendation and will likely not approve the therapy in August 2024.

Unmet need and commercial opportunity for novel PTSD treatments remain high

About 8% of U.S. adults experience PTSD in their lifetime ,and current therapies are insufficient to treat PTSD (based on Clarivate's PMR), thus, commercial opportunity for novel emerging therapies offering superior response and remission rates to current therapies patients remains high.

PTSD pipeline contains many psychedelic and psychedelic-like agents

While MDMA is the first agent to be submitted for approval, the PTSD pipeline holds several other psychedelic agents in Phase 2 or earlier. Even if not approved this year, we expect Lykos to continue development of this agent given the promising results seen in trials and the high need for better PTSD therapies. If the methodological issues and safety/substance abuse concerns are resolved, it could prove a valuable addition to the PTSD armamentarium and set a standard for future psychedelic development in PTSD and other psychiatric conditions.

About the author

Matthew D Litke, M.S.

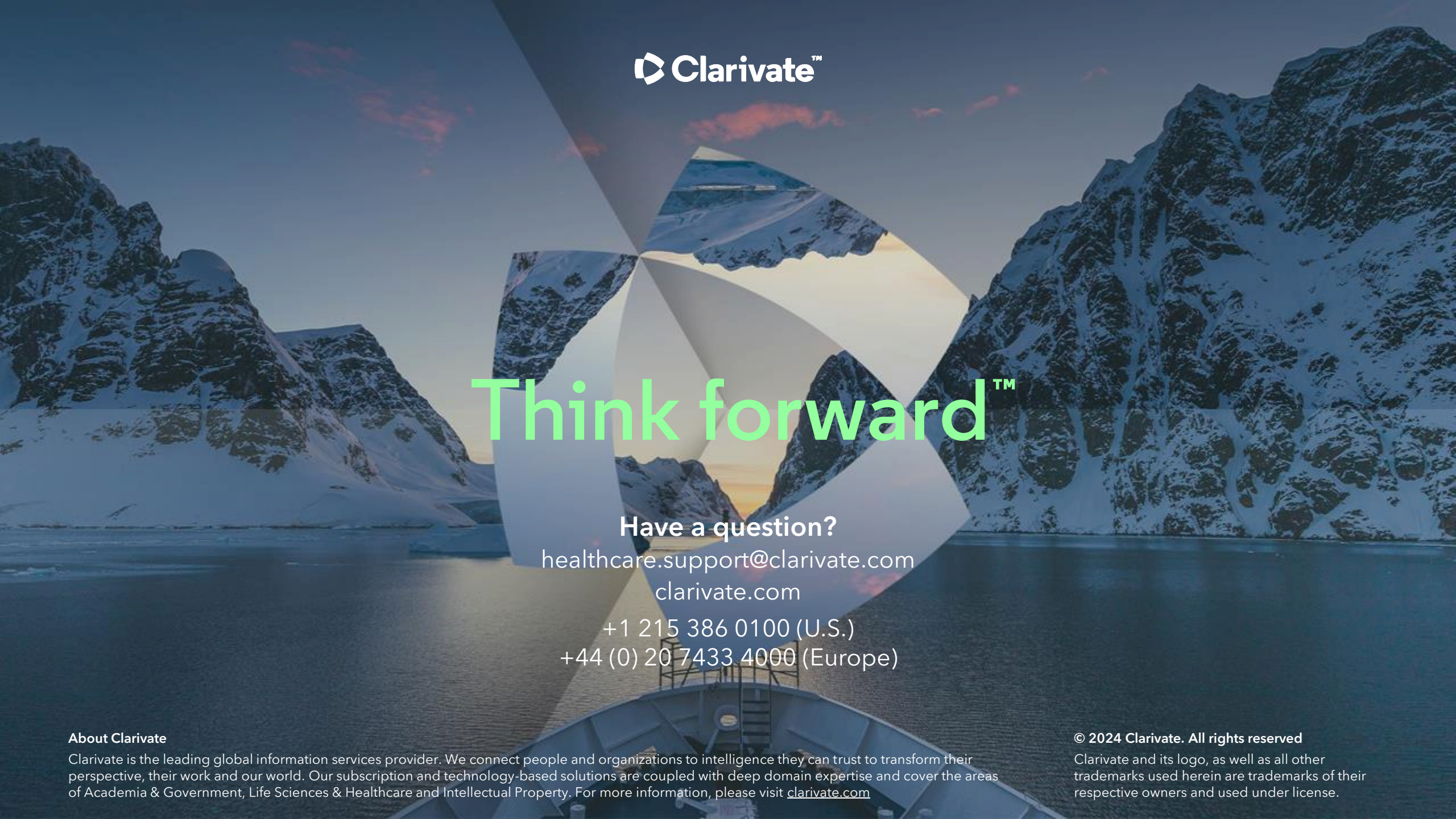
Lead Healthcare Research & Data Analyst

Mr. Litke supports Clarivate's Treatment Algorithms Claims Data Analysis report series, in addition to authoring syndicated content in the CNS and ophthalmology therapy areas. He holds a B.S. in biochemistry and molecular biology from Penn State University and an M.S. in psychology from Villanova University.

Matthew.Litke@clarivate.com

Clarivate coverage of PTSD

- Executive Insights | Post-Traumatic Stress Disorder (US) (published in 2024)
- Treatment Algorithms: Claims Data Analysis | Post-Traumatic Stress Disorder (US) (published in 2024)
- Unmet Need | Moderate to Severe Post-Traumatic Stress Disorder (US/EU) (published in 2024)
- Special Topics | Novel Drugs in Psychiatry (US) (published in 2023)



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healthcare.support@clarivate.com
clarivate.com
+1 215 386 0100 (U.S.)
+44 (0) 20 7433 4000 (Europe)

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