



COMP360 achieves success in the initial phase of a pivotal study for treatment-resistant depression

Market Event Summary

Kawal Preet Kaur; Himanshu Jain | July 2025

COMP360's Phase 3 program in TRD is progressing well.

Overview

In June 2023, Compass Pathways announced positive early efficacy results for its Phase 3 COMP005 trial evaluating COMP360. This agent is a synthetic, high-purity formulation of psilocybin that acts as a partial agonist at multiple 5-HT receptors, including 5-HT1a, 5-HT2a, 5-HT1d, and 5-HT2c. With a primary focus on TRD, the psychedelic-based therapy has shown promising results in Phase 2b and Phase 3 trials.

Top-line results from the single-dose, monotherapy Phase 3 trial: COMP005

- **Trial structure:** The COMP005 trial consists of three parts: part A (blinded for 6 weeks), part B (blinded for 26 weeks), and part C (open-label from week 26 to week 52).
- **Primary endpoint achieved:** The randomized, double-blind, placebo-controlled part A, involving 258 patients, met its primary endpoint. A single dose of 25 mg of COMP360, in addition to psychological support, demonstrated a statistically significant reduction in depressive symptom severity, as measured by the MADRS score. The mean treatment difference was -3.6 points compared to placebo ($P < 0.001$) at week 6.
- **Safety profile:** The trial demonstrated a stable safety profile, with no new safety issues identified and no indications of suicidal ideation in the short term.

Market impact

Clarivate's takeaways

- **Novel treatments for TRD remain a critical unmet need** in mental health. TRD affects about 30% of patients with MDD, with patients suffering from persistent and severe symptoms, diminished QoL, high rates of suicide, and extensive functional impairment.
- **KOLs interviewed by Clarivate are enthusiastic about** a drug specifically designed for the TRD segment. However, they voiced concerns about certain limitations associated with COMP360, including its potential link to suicidality, the complexity of its administration, and the anticipated high OOP costs for patients.
- **Market reaction:** The decrease in MADRS score for the 25 mg dose in Phase 3 compared to placebo is roughly half of what was observed in the therapy's Phase 2b study when comparing the 25 mg dose to the 1 mg dose. Therefore, despite positive Phase 3 results, Compass Pathways shares experienced a dip following the release of the trial results. Nevertheless, the potential of COMP360 to be the first-to-market psychedelic therapy and to address unmet needs in mental health conditions will continue to attract investors.
- **Implications:** The clinical trial data thus far support COMP360's potential in offering rapid and durable relief for TRD patients, a population with limited treatment options. The therapy's Phase 3 program is progressing well, despite some delays, and is expected to lead to regulatory approval and commercialization. Its success would open the door to a new approach in mental health treatment.

About the authors



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Ms. Kaur has substantial experience in market research and competitive intelligence. On Clarivate's CNS/Ophthalmology team she is mainly involved in market research and forecasting for depression. She holds an M.B.A. in pharmaceutical management from Jamia Hamdard University.



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Mr. Jain has authored content for multiple psychiatry indications, including schizophrenia, major depressive disorder, and bipolar disorder. He has more than 15 years of experience working in market research and consulting firms. He earned his master's degree in pharmacology and toxicology from the National Institute of Pharmaceutical Education and Research and holds an Executive Post Graduate Diploma in International Business from the Indian Institute of Foreign Trade.

Clarivate coverage on Major depressive disorder

- Disease Landscape & Forecast: Major Depressive Disorder (G7), providing comprehensive market intelligence insights
- Epidemiology: diagnosed incidence and prevalence data of MDD across the G7 and emerging markets.
- Current Treatment: Physician Insights (EU5 and the United States), exploring prescribing trends among surveyed psychiatrists and primary care physicians.
- Treatment Algorithms: Claims Data Analysis | MDD (US), exploring prescribing trends via claims data analysis.
- Unmet Need: Treatment-Resistant Depression (US / EU), including an Excel-based target product profile simulator.
- Access & Reimbursement: MDD (US), providing insights on the impact of payer policy on prescribing behavior in MDD.



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