

Compass Pathways Announces Publication of Post-Hoc Analysis Demonstrating Distinction of COMP360 Trial Monitoring & Support from Psychotherapy

2026-07-16

- Post-hoc analysis of support methods used in an open-label Phase 2 COMP360 study showed monitoring and support provided during treatment administration sessions were minimal, non-directive and distinct from conventional conceptions of psychotherapy
- Findings published in the **Journal of Psychopharmacology**

LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health, today announced the publication of a post-hoc analysis of support methods used in an open-label Phase 2 study of investigational COMP360 synthetic psilocybin treatment in patients with post-traumatic stress disorder (PTSD). Documented speech production between participants and support providers during treatment administration sessions showed minimal interaction. Monitoring and support were linked by patients to presence, availability, reassurance and validation. The limited and non-directive nature of these interactions distinguishes this form of support from therapeutic dialogues typically used in conventional psychotherapy or other trauma-focused psychological treatments.

“The monitoring and support we’ve incorporated across our COMP360 trials in both treatment-resistant depression and PTSD is designed to safeguard patients and protect data integrity during psychedelic treatment. Patients themselves have indicated they value a reassuring presence, but the key aspects of the experience are self-directed,” said Dr. Guy Goodwin, Chief Medical Officer of Compass Pathways. “These findings reinforce that the rapid and durable symptom improvement observed in the open-label Phase 2 PTSD trial was attributable to the psilocybin drug experience. It is incorrect to describe the treatment we are developing as psilocybin-assisted

psychotherapy. We are happy to see these results published in the Journal of Psychopharmacology and excited to continue building upon the existing body of evidence supporting the transformative potential of COMP360 for the treatment of TRD and PTSD.”

Key Findings & Qualitative Themes

- The vast majority (78%) of the administration session was spent in silence.
- Support was minimal, yet relevant to patients’ feelings of safety and stability. Several participants described the support providers as a reliable and available resource if needed, but largely out of their awareness during treatment.
- Non-directive support strategies promoted autonomy through the introspective psychedelic state. Participants were empowered to sustain inward focus and self-navigate the treatment without the support provider leading, redirecting or reinterpreting the experience in any way.
- Primary modes of support included reassurance and validation from physical proximity.

These findings were published in the **Journal of Psychopharmacology**.

Compass Clinical Trial Monitoring & Support

Compass has developed a systematic training and mentoring program to ensure and measure quality and consistent monitoring and support for participants across all COMP360 trials in treatment-resistant depression (TRD) and PTSD. Support providers for trials are trained using a manualized approach based on historical clinical experience and regulatory guidance, reinforced with ongoing mentorship. Support strategies include breath and body awareness, short verbal cues, and physical proximity.

About Post-Traumatic Stress Disorder

Post-Traumatic Stress Disorder (PTSD) is a serious mental health condition that can develop after exposure to **traumatic events** such as personal assault, combat, natural disasters, or serious accidents. Characterized by **symptoms** such as intrusive memories, avoidance behaviors, negative shifts in mood and cognition, and heightened arousal, PTSD affects approximately **five percent** of adults in the U.S. annually. Symptoms may appear within months of the trauma or be delayed, and they must persist for **over a month** and interfere with daily functioning to meet diagnostic criteria.

PTSD can impact anyone, though **certain populations**—including veterans, first responders, and survivors of abuse—are at elevated risk. Individuals living with PTSD frequently experience **comorbid mental health conditions**, most commonly, depression, anxiety disorders, substance use disorders, as well as a significantly increased risk of

suicide. These overlapping conditions can intensify distress and complicate treatment.

Affecting **13 million people** in the U.S. each year, PTSD remains an underserved condition. There are currently only two FDA-approved medications for PTSD. This limited pharmacological landscape underscores the urgent need to advance care for patients experiencing this debilitating condition.

About Compass Pathways

Compass Pathways plc (Nasdaq: CMPS) is a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. We are motivated by the need to find better ways to help and empower people with serious mental health conditions who are not helped by existing treatments. We are pioneering a new paradigm for treating mental health conditions focused on rapid and durable responses through the development of our investigational COMP360 synthetic psilocybin treatment, potentially a first in class treatment. COMP360 has Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) and has received Innovative Licensing and Access Pathway (ILAP) designation in the UK for treatment-resistant depression (TRD).

Compass is headquartered in London, UK, with offices in New York in the U.S. We envision a world where mental health means not just the absence of illness but the ability to thrive.

Forward-looking statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. In some cases, forward-looking statements can be identified by terminology such as “may”, “might”, “will”, “could”, “would”, “should”, “expect”, “intend”, “plan”, “objective”, “anticipate”, “believe”, “contemplate”, “estimate”, “predict”, “potential”, “continue” and “ongoing,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements include express or implied statements relating to, among other things, statements regarding our business strategy and goals; the potential for our clinical trials to support regulatory filings and approvals; our expectations regarding the safety or efficacy of our investigational COMP360 psilocybin treatment, including as a treatment for treatment of TRD and PTSD; any implication that past results will be predictive of future results; our ability to obtain regulatory approval and adequate coverage and reimbursement; our ability to transition from a clinical-stage to a commercial-stage organization and effectively launch a commercial product, if regulatory approval is obtained; and our expectations regarding the benefits of our investigational COMP360 psilocybin treatment. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Compass’s control and which could cause actual

results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements.

These risks, uncertainties, and other factors include, among others: uncertainties associated with risks related to clinical development which is a lengthy and expensive process with uncertain outcomes, and therefore our clinical trials may be delayed or terminated and may be more costly than expected; the results of early-stage clinical trials of our investigational COMP360 psilocybin treatment in PTSD may not be predictive of the results of our planned late-stage clinical trial in PTSD; our need for substantial additional funding to achieve our business goals and if we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our clinical trials; our efforts to obtain marketing approval from the applicable regulatory authorities in any jurisdiction for our investigational COMP360 psilocybin treatment may be unsuccessful; and our efforts to commercialize and obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment, if approved, may be unsuccessful; and those risks and uncertainties described under the heading “Risk Factors” in Compass’s most recent annual report on Form 10-K or quarterly report on Form 10-Q, and in other reports we have filed with the U.S. Securities and Exchange Commission (“SEC”), which are available on the SEC’s website at www.sec.gov. Except as required by law, Compass disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Compass’s current expectations and speak only as of the date hereof.

Enquiries

Media: Dana Sultan-Rothman, media@compasspathways.com

Investors: Stephen Schultz, stephen.schultz@compasspathways.com, +1 401 290 7324

Source: Compass Pathfinder Limited