

Compass Pathways Announces Publication of Results from Phase 2 Study of COMP360 Psilocybin for Post-Traumatic Stress Disorder

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- Open-label Phase 2 study shows a single 25 mg COMP360 psilocybin dose was well tolerated, with no serious adverse events observed, and indicated both rapid and durable improvement in symptoms from baseline observed out to 12 weeks following a single administration
- 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 results from an open-label Phase 2 study evaluating the safety and tolerability of a single-dose of 25 mg of investigational COMP360 synthetic psilocybin treatment in 22 patients with post-traumatic stress disorder (PTSD). The Phase 2 study findings, previously disclosed in May 2024, show that COMP360 was well tolerated and indicated both rapid and durable improvement in symptoms from baseline observed out to 12 weeks following a single administration. The international Phase 2 study was conducted across three sites in the U.K. and the U.S.

"Affecting approximately 13 million people in the U.S., and with only two approved treatments in the past two decades, post-traumatic stress disorder (PTSD) represents an area of profound unmet need with limited innovation to date," said Dr. Guy Goodwin, Chief Medical Officer. "We are proud to see the results from this Phase 2 study published in the Journal of Psychopharmacology. Based on the highly encouraging results, we are finalizing late-stage clinical trial designs and look forward to evaluating the full potential of COMP360 for the treatment of PTSD."

The study findings were published in the **Journal of Psychopharmacology**.

Phase 2 Primary and Key Secondary Endpoints

- Administration was well tolerated, with no serious adverse events observed. There were no treatment-emergent serious adverse events. The most common treatment-emergent adverse events included headache (n=11 or 50.0%), nausea (n=8 or 36.4%), crying (n=6 or 27.3%), fatigue (n=6 or 27.3%), and visual hallucinations (n=5 or 22.7%).
- Durable improvement in symptoms from baseline observed out to 12 weeks following a single administration. Improvement in mean CAPS-5 total score from a baseline of 47.5 was observed (29.9 point reduction at week 4 and 29.5 point reduction at week 12).
- Improvement over time in Sheehan Disability Scale (SDS) measure of functional impairment over 12 weeks. From a mean SDS total score of 22.7 at baseline, there was a 11.7 point reduction at week 4 and a 14.4 point reduction at week 12.
- High and sustained rates of response and remission relative to baseline, with early onset of symptom improvement. Response, as defined by patients experiencing a ≥ 15 -point reduction from baseline on CAPS-5 total score, was 81.8% at week 4 and 77.3% at week 12. Remission, as defined by CAPS-5 total score of ≤ 20 , was 63.6% at week 4 and 54.5% at week 12.

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. Our focus is on improving the lives of those who are living with mental health challenges and who are not helped by existing standards of care. We are pioneering the development of a new model of psilocybin treatment, in which our proprietary formulation of synthetic psilocybin, COMP360, is administered in conjunction with psychological support. COMP360 has Breakthrough Therapy designation from the US 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; our plans and expectations regarding our planned late-stage clinical trial in PTSD; the potential for the pivotal phase 3 program in TRD, the planned late-stage trial in PTSD, or any future 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 full results and safety data from our first Phase 3 study in TRD, COMP005, or the results and safety data from our second Phase 3 study in TRD, COMP006, may not be consistent with the preliminary results to date; 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, the prospectus supplement related to the proposed public offering we plan to file 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.

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