

# Compass Pathways Announces Dosing Complete for All Participants in Part A of Phase 3 COMP005 Trial of COMP360 Psilocybin for Treatment-Resistant Depression

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## Highlights:

- Participants received a single dose of either 25 mg of COMP360 or placebo
- On track for disclosure of top-line 6-week primary endpoint results in late June

LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to accelerating patient access to evidence-based innovation, today announced that all participants have completed dosing in Part A of the COMP005 phase 3 trial for treatment resistant depression (TRD). Following pre-dosing activities, including washout from anti-depressant medications, if needed, participants received a single dose of either 25 mg of COMP360 or placebo. The Company is on track to disclose top-line 6-week primary endpoint results in late June.

“Completing dosing of all participants in Part A of our 005 trial marks a critical milestone in our mission to address the pressing unmet need in treatment resistant depression,” said Kabir Nath, CEO Compass Pathways. “We are proud of this achievement which reflects our team’s commitment to scientific rigor, operational excellence and potential to deliver a new treatment option to patients who have long been underserved. We are incredibly grateful to the participants, investigators and clinical sites that are making this study possible. We look forward to sharing the results of the 6-week primary endpoint in late June.”

About the phase 3 COMP005 trial

To date, the COMP005 trial is the largest, multi-center study of an investigational, synthesized psilocybin to complete recruitment and will be the first pivotal program to report the efficacy of synthesized psilocybin for the treatment of TRD. In this randomized, double-blinded, placebo-controlled study, 258 participants with moderate-to-severe depression that have not responded to at least two or more prior treatments were dosed across 32 sites in the United States. This study aims to assess the efficacy and safety of a single dose of COMP360 25 mg versus placebo for reducing symptom severity in TRD.

The trial is comprised of three parts: Part A, which is blinded through 6 weeks, Part B, which remains blinded through week 26, and Part C, which is open-label from week 26 to week 52.

COMP360 is a synthesized, proprietary formulation of psilocybin under investigation as a treatment for certain difficult-to-treat mental health conditions.

## About treatment resistant depression (TRD)

Depression is one of the most common mental health disorders and the largest contributor to disability globally according to the World Health Organization. Approximately **300 million people**, representing 5% of the adult population, suffer from major depressive disorder (MDD) worldwide.

Approximately **one-third** of patients with MDD aren't helped by existing therapies and are at high risk of developing treatment-resistant depression. TRD is generally defined as an inadequate response to two or more appropriate courses of approved medications. TRD has a significantly greater impact on individuals compared to MDD, leading to residual symptoms, poorer quality of life, increased comorbidities, higher mortality, and an increased risk of suicide.

## 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 synthesized psilocybin treatment, potentially a first in class treatment. 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 and San Francisco in the US. 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 phase 3 trials in TRD, including our expectations regarding the time periods during which the results of the two Phase 3 trials will become available; our expectations regarding the time periods during which results of other pivotal trials of synthesized psilocybin will become available; the potential for the pivotal phase 3 program in TRD, any future trials in PTSD, or other 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; our ability to obtain regulatory approval and adequate coverage and reimbursement; and our ability to transition from a clinical-stage to a commercial-stage organization and effectively launch a commercial product, if regulatory approval is obtained. 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 may not be predictive of the results of later stage clinical trials; 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; 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](http://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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