

Compass Pathways Announces Completion of Recruitment for the Phase 3 COMP005 Trial of COMP360 Psilocybin for Treatment-Resistant Depression

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Highlights:

- Screening closed for all sites and final participants being scheduled for dosing
- On track for top-line 6-week primary endpoint results in late Q2

LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to accelerating patient access to evidence-based innovation, today announced the completion of recruitment in the COMP005 phase 3 trial for treatment resistant depression (TRD). The final participants are completing pre-dosing activities, including washout from anti-depressant medications, if necessary, and those eligible will receive a dose of either 25 mg of COMP360 or placebo.

“We are pleased that recruitment is complete in the 005 trial, bringing us one-step closer to delivering COMP360 as a potential first-in-class psilocybin treatment for patients with treatment resistant depression,” said Kabir Nath, Chief Executive Officer of Compass Pathways. “We await completion of dosing of the last participant, a milestone that we will also announce in the coming weeks, and we look forward to sharing the results of the 6-week primary endpoint in late Q2.”

COMP360 is a synthetic form of psilocybin under investigation as a treatment for certain difficult-to-treat mental health conditions when administered with psychological support.

TRD is a condition in which individuals with major depressive disorder do not respond adequately to at least two different treatments. Depression is the leading cause of disability and ill health worldwide. Up to two-thirds of people with depression are not helped by the first antidepressant medication they try. Up to a third of people with depression are failed by multiple attempts at treatment.

The pivotal phase 3 clinical program of COMP360 psilocybin treatment in TRD is the largest randomized, controlled, double-blind psilocybin treatment clinical program ever conducted. Top-line 6-week (primary endpoint) COMP005 data is expected late in the second quarter 2025 and 26-week COMP005 data is expected once all participants in the COMP006 trial have completed part A of the COMP006 trial. The COMP006 26-week data is expected in the second half of 2026.

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 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. Our vision is a world of mental wellbeing.

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 number of participants that will be dosed and the time periods during which the dosing of all participants will be completed and the results of the two Phase 3 trials 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; participants who have completed screening may not complete pre-dosing activities and enroll in our COMP005 trial; 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. 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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