NEWS RELEASE

# Compass Pathways Announces Publication of Results from COMP004 Study on COMP360 Psilocybin for Treatment-Resistant Depression

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## Highlights:

- 52-week observational follow-up study from Phase 2b reveals single 25 mg COMP360 psilocybin dose offers longer-term antidepressant effects compared to lower doses, with average efficacy for a single dose of 25mg lasting about 12 weeks and substantially longer in a subgroup
- Findings published in the March edition of the Journal of Clinical Psychiatry

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 publication of results from the COMP004 study, an observational 52-week follow-up from the Phase 2 COMP001 and COMP003 trials of COMP360 psilocybin treatment in patients with treatment-resistant depression (TRD). The COMP004 study's findings suggest that over a 52-week period, a single administration of 25 mg COMP360 psilocybin demonstrated a longer maintenance of antidepressant effects compared to the 1 mg and 10 mg doses.

The results of COMP004 build upon previous findings from the Phase 2b trial COMP001, which showed that a single 25mg dose of COMP360 psilocybin was associated with a rapid and highly statistically significant reduction in depressive symptoms compared to COMP360 1mg dose after three weeks ($p<0.001$), with durable response for up to 12 weeks.

## Key COMP004 findings

- Durable improvement in symptoms observed. The analysis of all patients in COMP001 revealed a longer time

to relapse for patients receiving 25 mg compared with 10mg and 1 mg, with the median time to a depressive event of 92 days for the 25 mg dose group, 83 days for the 10 mg and 62 days for the 1 mg group.

- Extended benefit for a subgroup.A post hoc analysis revealed a substantial difference in time to depressive event for those who enrolled in COMP004 from COMP001 in the 25 mg group compared to the 10mg and 1mg groups, with median times of 189 days for the 25 mg group, 43 days for the 10 mg group, and 21 days for the 1 mg group.
- Safety monitoring. COMP360 was generally well tolerated. Three participants reported experiencing a treatment emergent serious adverse event (TESAE) post-enrollment to COMP004, occurring more than 6 months after a single dose administration and all deemed unrelated to study drug.

These COMP004 study data were published in the March edition of the **Journal of Clinical Psychiatry.**

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.

“Treatment-resistant depression is a major public health challenge, affecting approximately 100 million people worldwide, and it is well understood that there is an urgent need for differentiated treatment options,” said Dr. Guy Goodwin, Chief Medical Officer. “This study together with the Phase 2b (COMP001) suggest the potential of COMP360 to provide rapid and durable clinical benefits from a single administration. We continue to explore the full profile of COMP360 in our ongoing Phase 3 clinical development program and we look forward to seeing the first phase 3 data from our COMP005 trial in the second quarter.”

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 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 the COMP004 Trial

The COMP004 trial is a 52-week observational follow-up study on sixty-six participants from COMP001 (n=58 of which 22 participants were in the 25 mg arm, 19 participants were in the 10 mg arm and 17 participants were in the

1 mg arm) and COMP003 (n=8) trials to explore the long-term efficacy and safety of the three different doses of psilocybin (1 mg, 10 mg, and 25 mg) administered to patients with TRD as a monotherapy in COMP001 and 25 mg psilocybin administered as an adjunct to an SSRI in COMP003. Following completion of COMP001 or COMP003, as applicable, study participants had the option to enroll in COMP004 and there was a low rate of enrollment into COMP004. The analyses based solely on participants who enrolled in COMP004 are limited by the resulting selection bias.

## 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 time periods during which 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; 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, including that the results from this long-term follow-up study may not be predictive of the results for our phase 3 program in TRD; 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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