NEWS RELEASE

Compass Pathways Successfully Achieves Primary Endpoint in Second Phase 3 Trial Evaluating COMP360 Psilocybin for Treatment-Resistant Depression

2026-02-17

- Two highly statistically significant positive Phase 3 trials confirm highly differentiated profile for COMP360, demonstrating a level of clinical effect that has historically been extremely difficult to achieve in TRD
- COMP360 is the first classic psychedelic[1] to consistently achieve a highly statistically significant result and clinically meaningful effect, with a generally well-tolerated and safe profile
- In COMP006, two doses of COMP360 25 mg versus 1 mg demonstrated a highly statistically significant and clinically meaningful reduction in symptom severity as measured by MADRS[2] with a mean difference of -3.8 comparing 25 mg to 1 mg ($p<0.001$)[3]
- Clinically meaningful reduction in MADRS (≥ 25%) observed in significant number of participants in 25mg arm of both trials with 25% in COMP005 and 39% in COMP006
- Statistically significant rapid onset from the day following administration maintained at all measured timepoints through Week 6 in both clinical trials in the 25 mg arm
- In COMP005, participants who achieved a clinically meaningful reduction in MADRS at Week 6 with COMP360 25 mg maintained durability of effect at least through Week 26 after just one or two doses
- Across both Phase 3 trials to date, COMP360 is demonstrating a generally well-tolerated and safe profile with no unexpected safety findings
- Compass has requested a meeting with the FDA to discuss a rolling submission and review and expects to

complete an NDA submission in Q4

- Compass management will host a webinar on February 17th at 8:00 am ET

LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to accelerating patient access to evidence-based innovation, announced today the successful achievement of the primary endpoint in the ongoing Phase 3 COMP006 trial, the second of two Phase 3 trials, which is evaluating two fixed doses of COMP360, a synthetic, proprietary formulation of psilocybin, for treatment-resistant depression (TRD). The primary endpoint was the difference in change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) scores between the 25 mg and 1 mg groups at Week 6. Two fixed doses – administered 3 weeks apart – of COMP360 25 mg versus 1 mg demonstrated a highly statistically significant reduction in symptom severity with a p-value of <0.001 and a clinically meaningful difference of -3.8 points in change at the primary endpoint.

Across COMP005 and COMP006 to date, COMP360 is demonstrating a generally well-tolerated and safe profile, with treatment-emergent adverse events (TEAEs) being mild or moderate in severity, and the vast majority resolving within 24 hours. The data confirms a statistically significant rapid onset from the day following administration and maintained at all measured timepoints through Week 6 in both clinical trials in the 25 mg arm. COMP005 suggests that participants who demonstrated a clinically meaningful reduction in MADRS maintained durable treatment effect at least through Week 26, after just one or two doses. Retreatment with a second dose was well-tolerated, with a consistent safety profile.

Compass has submitted a request for a meeting with the U.S. Food and Drug Administration (FDA) to discuss a rolling submission and review.

“Across three robust, well-designed and well-executed clinical trials involving more than 1,000 participants, we have now demonstrated consistent, highly statistically significant results at the primary endpoint and a clinically meaningful effect. This is a remarkable achievement for the field of psychiatry - especially in the TRD population, where proving benefit has historically been extraordinarily challenging,” said Kabir Nath, Chief Executive Officer at Compass Pathways. “These data strengthen our conviction in the highly differentiated profile for COMP360 and given the urgent need for new treatments in TRD, we are advancing our discussions with the FDA, with the goal of submitting an NDA in Q4 and securing approval.”

“TRD patients have extremely limited treatment options, and the unmet need remains profound. The promising clinical profile of COMP360 reinforces our belief in its potential to set a new standard of care for this population,” said Dr. Guy Goodwin, Chief Medical Officer at Compass Pathways. “These results redefine rapidity and durability for TRD patients with onset as early as the next day and, for those who respond, effects from just one or two doses lasted at least through 26 weeks, alongside a well-tolerated safety profile. Across the very limited TRD treatment

landscape, this potential treatment truly stands out for its extremely rapid and sustained efficacy. We are incredibly grateful to the participants, investigators, and clinical trial staff for their invaluable contributions to our trials and for making this significant progress possible."

Key Findings

Efficacy Profile

COMP005

- Primary endpoint of Part A (previously disclosed in June 2025): Single dose of COMP360 25 mg versus placebo with a mean treatment difference of -3.6 points, 95% CI [-5.7, -1.5]; p<0.001 at Week 6 [4]
- For participants who had a clinically meaningful reduction in MADRS (≥ 25%), a statistically significant rapid onset from the day following administration was maintained at all measured timepoints through Week 6 in the 25 mg arm
- 25% of participants in the 25 mg arm achieved a clinically meaningful reduction in MADRS (≥ 25%) at Week 6 with durability lasting out through 26 weeks after just one or two doses of 25 mg
- Over 40% of those who achieved a clinically meaningful reduction in MADRS but had not remitted by 6 weeks went into remission after the second dose in Part B

COMP006

- Primary endpoint of Part A: Two doses of COMP360 25 mg versus 1 mg with a mean treatment difference of -3.8 points, 95% CI [-5.8, -1.8]; p<0.001 at Week 6
- 39% of participants in the 25 mg arm achieved a clinically meaningful reduction in MADRS (≥ 25%) at Week 6
- For participants who achieved a clinically meaningful reduction in MADRS (≥ 25%), a statistically significant rapid onset from the day following administration was maintained at all measured timepoints through Week 6 in the 25 mg arm
- The 26-week data (Part B) from COMP006 is expected in early Q3 2026

Safety Profile

The Chair of the independent Data Safety Monitoring Board (DSMB) provided the following statement: "Based on the latest review of this data for the 005 and 006 TRD studies, safety findings are consistent with previous studies of COMP360 and there are no new, unexpected or concerning safety findings. Safety findings are consistent with the known profile of the study drug (a classical psychedelic) and the treatment-resistant depression patient population. From this review of the data, there is no evidence of a clinically meaningful imbalance between treatment arms in suicidality in either study."[5]

COMP005

In the 25 mg arm, (Part A and B):

- Most TEAEs occurred on the days of study drug administration (66%), with the vast majority (88%) resolving within a day
- Most common TEAEs reported were headache, nausea and visual hallucination
- There were 11 treatment-emergent serious adverse events (SAEs) from 8 participants (5%) overall

COMP006

In the 25 mg arm (Part A):

- Most TEAEs occurred on the days of study drug administration (73%) with the vast majority (83%) resolving within a day
- Most common TEAEs were headache, nausea, anxiety and visual hallucination
- There were 6 treatment-emergent serious adverse events (SAEs) from 6 participants (2%) overall

Across both trials, for the data available to date, the rate for SAE suicidal ideation was less than 1%. There was only one event of SAE suicidal behavior, which occurred in the 1 mg arm in COMP006.

Live Webcast

Compass management will host a live audio webcast on February 17th at 8:00 am ET. The webcast will be accessible at this link: **https://lifescievents.com/event/hz02j0rpw/**

A replay of the webcast will be accessible for 30 days following the event.

About the COMP360 Phase 3 Program

The COMP360 program aims to evaluate the safety and efficacy of COMP360 psilocybin, a synthetic, proprietary formulation of psilocybin under investigation for difficult-to-treat mental health conditions. There are two pivotal Phase 3 trials, COMP005 and COMP006, evaluating the efficacy of COMP360 for treatment-resistant depression (TRD).

The ongoing COMP005 trial is a randomized, double-blind, placebo-controlled study, with 258 dosed participants across the United States and is assessing the efficacy and safety of a single dose of 25 mg COMP360 versus placebo for reducing symptom severity in TRD (COMP360 25 mg: n=171; placebo: n=87).The trial is comprised of three parts:

Part A, which was blinded through 6 weeks; Part B, which has recently concluded and was blinded through week 26; and Part C, which contains an open-label treatment part from week 26 to 52.

The ongoing COMP006 trial, running in parallel to the COMP005 trial, is a randomized, double-blind study with 581 dosed participants across North America and Europe and is comparing the efficacy and safety of two fixed doses, taken three weeks apart, of 25 mg COMP360 to 10 mg COMP360 and 1 mg COMP360 (25 mg: n=296; 10 mg: n=142; 1 mg: n=143). The trial is comprised of three parts: Part A, which has recently concluded and was blinded through 9 weeks, Part B which remains blinded through week 26, and Part C, which contains an open-label treatment part from week 26 to 52.

About treatment resistant depression (TRD)

Depression, one of the most common mental health disorders, significantly impacts relationships, work performance, overall quality of life, and is associated with an increased risk of suicide. **Major depressive disorder** (MDD) has been ranked as the third cause of the burden of disease worldwide in 2008 by the World Health Organization (WHO), which has projected that this disease will rank first by 2030.

It is estimated that approximately 4 million patients in the U.S. with MDD live with TRD[6]. **TRD** is broadly 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 compared to non-treatment resistant MDD.

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; our expectations and projections about the company’s future cash needs and financial results; our expectations regarding the safety or efficacy of our investigational COMP360 psilocybin treatment, including as a treatment for treatment of TRD or PTSD; our plans and expectations regarding our clinical trials, including our phase 3 trials in TRD and our phase 2b/3 trial in PTSD; our expectations regarding the time periods for the release of data from Part B of the COMP006 Phase 3 trial for TRD; our expectations regarding discussions with the FDA, including discussions regarding potential NDA acceleration strategies, including potential for rolling NDA submission and review for COMP360 psilocybin treatment in TRD; our expectations regarding potential commercial launch timelines and our commercial readiness; the potential for the pivotal phase 3 program in TRD to support regulatory filings and approvals on an accelerated basis or at all; 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, on an accelerated timeline or at all; 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 Phase 3 clinical trials in TRD may not be consistent with the preliminary results to date; 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 acceleration strategies for our NDA submission may not be successful; FDA may ultimately disagree with our proposal for a rolling NDA submission and may not permit us to utilize the rolling review process; our efforts to obtain marketing approval from FDA or regulatory authorities in any other 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; the risk that our strategic collaborations will not

continue or will not be successful; and our ability to retain key personnel; 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.

References

1. For the definition of classic psychedelic, see Vollenweider, F.X. and Smallridge, J.W., 2022. Classic psychedelic drugs: update on biological mechanisms. Pharmacopsychiatry, 55(03), pp.121-138
2. Montgomery-Åsberg Depression Rating Scale
3. Data on file
4. Data on file
5. Statement on file from the DSMB Chair, dated February 11, 2025
6. Data on file

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Source: Compass Pathfinder Limited