Compass Pathways' New 52-Week Topline Open-Label Data from Phase 3 COMP005 Trial Demonstrates Additional Benefit from Another COMP360 Dose in Part C Extending Durability Out to 1 Year

- *Notable additional benefit observed with an added reduction in MADRS[1] score leading to an average 13-point reduction from baseline at Week 52 with durability extended out to 1 year for participants who were randomized to the 25 mg arm and received an additional dose*
- *For participants randomized to Placebo arm who received first dose of COMP360 25 mg in open-label Part C, data further reinforces that a single 25 mg dose can produce rapid onset, meaningful effect and durability*
- *For all participants in Part C who received a 25 mg open-label dose, strong response and remission rates were observed with 40%-45% responders[2] and approximately 30% remitters[3] across all timepoints 6 weeks post the Part C dose*
- *This 1-year data further supports the belief that, if approved, COMP360 could establish a new standard of care in TRD that can be life-changing for patients - moving beyond daily or frequent administration toward an option that could provide durable benefit with just a few treatments a year*
- *COMP360 safety profile in Part C consistent with Parts A and B. COMP360 continues to demonstrate a generally well-tolerated and safe profile with no new safety findings*
- *Rolling NDA submission and review underway and final submission on track to be completed in Q4*
- *Continue to expect commercial launch in first half of 2027*

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LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to unlocking urgently needed new treatment options in mental health care, announced today the topline 52-week results (Part C) from its Phase 3 COMP005 trial of COMP360, a synthetic, proprietary formulation of psilocybin, for treatment-resistant depression (TRD) which further support COMP360's differentiated profile and potential for long lasting benefit. The open-label Part C data demonstrate four important findings: first, notable additional benefit was observed with an added reduction in MADRS score leading to an average 13-point reduction from baseline at Week 52 and extended out to 1 year for participants who were randomized to the 25 mg arm and received an additional dose in Part C; second, for participants in the Placebo arm who received their first dose of COMP360 25 mg in Part C, these findings further reinforce that a single dose of 25 mg has the potential to produce rapid onset, meaningful effect and durability; third, for all participants in Part C who received a 25 mg dose, strong response and remission rates were observed with 40%-45% responders and approximately 30% remitters across all timepoints in the 6 weeks post the Part C dose; and finally, the COMP360 safety profile in Part C is consistent with Parts A and B and continues to show a generally well-tolerated and safe profile with no new safety findings.

"COMP360 has now demonstrated rapid onset, substantial magnitude of effect and sustained durability through one year with just a few doses. This emerging clinical profile is unmatched in

TRD and puts COMP360 in a league of its own," said Kabir Nath, Chief Executive Officer of Compass Pathways. "We are excited for what this means for TRD patients and for those who care for them and the potential to move beyond treatments that require daily or frequent administration. As we continue to advance COMP360 for patients, our rolling NDA submission and review are well underway, with final NDA submission expected in the fourth quarter and launch expected in the first half of next year, subject to FDA approval. With a robust clinical package, and growing patient and provider anticipation for COMP360 as a much-needed treatment for TRD, Compass is well-positioned and ready to deliver."

Key Findings

The COMP005 trial was a randomized, double-blind, placebo-controlled study, that enrolled 258 participants in the United States assessing the safety and efficacy of a single dose of 25 mg COMP360 versus placebo for reducing symptom severity in TRD.

The trial was comprised of three parts:

- In Part A, blinded through Week 6, eligible participants were randomized (2:1) to receive a single dose of 25 mg of COMP360 or placebo
- In Part B, blinded from Weeks 6 to 26, eligible participants could receive an additional dose of the same treatment to which they were originally randomized
- In Part C, open-label from Week 26 to 52, eligible participants from both dosing arms could receive a single dose of 25 mg

Approximately 70% of the study participants continued beyond Week 26 and entered Part C:

- 25 mg Arm: Approximately 80% (n=90) who entered Part C received an additional open-label dose; this was their second or third dose depending on whether they received an additional dose in Part B
- Placebo Arm: Approximately 90% (n=52) who entered Part C received an open-label 25 mg dose; this was their first dose of COMP360 25 mg given they received placebo in parts A and B

Figure 1: 25 mg participants who continued through Part C

For participants who had originally been randomized to the 25 mg arm (the blue line in Figure 1), and continued into Part C and received another dose:

- Notable additional benefit observed at all Part C timepoints through Week 52, with additional meaningful reduction in MADRS beyond what had been observed in Parts A and B, with an average 13-point reduction from baseline at Week 52
- Given participants in 25 mg arm had one or two prior doses, these findings provide continued evidence that an additional dose of COMP360 25 mg may further deepen clinical response and extend its durability out to 1 year

Figure 2: Placebo participants who continued through Part C

For participants who had originally been randomized to the Placebo arm (the grey line in Figure 2) and continued into Part C, and were eligible to receive their first dose of COMP360 25 mg in this open-label portion of the trial:

- Data provides further evidence that a single dose of COMP360 25 mg has the potential to produce rapid onset, meaningful effect, and durability
- Meaningful average reduction of 10 points from baseline in MADRS at end of Part C from one dose

Figure 3: Response and remission rates post open-label treatment

For all participants who received a 25 mg COMP360 dose in open-label Part C, whether they originally were in the Placebo arm and this was their first dose, or they were originally in the 25 mg arm and this was their second or third dose:

- 40%-45% response rates (Responder: ≥50% decrease in total score from baseline) were observed between Day 1 and Week 6 following COMP360 25 mg Part C treatment
- Approximately 30% remission rates (Remitter: ≤12 MADRS total score and no single item ≥4) were observed between Day 1 and Week 6 following COMP360 25 mg Part C treatment

COMP360 safety profile in Part C is consistent with Parts A and B. COMP360 continues to demonstrate a generally well-tolerated and safe profile, with no new safety signals observed.

“These 52-week results show COMP360, if approved, has the potential to be truly life changing for TRD patients. The consistent, rapid onset, pronounced magnitude of effect and durability to one year are remarkable to see, especially in such a chronic TRD population,” said Dr. Guy Goodwin, Chief Medical Officer of Compass Pathways. “TRD remains one of the most challenging conditions in psychiatry to treat, and these results further reinforce COMP360’s highly differentiated clinical profile. Across the 52-week study period, participants experienced cumulative and sustained reductions in depressive symptoms, which represent a significant advancement for the field. Importantly, we are especially excited to see the trends in the open-label Part C of this trial, with continued benefit and high rates of response and remission, which we believe is a closer representation of how COMP360 will be used in real-world clinical practice. For people living with TRD, and for the clinicians committed to helping them, we believe COMP360 has the potential to reshape expectations for treatment and provide long-term benefit.”

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 COMP006 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). There is a potential for a total of 4 doses of COMP360 across a 52-week period. The trial is comprised of three parts: Part A, which was blinded through 9 weeks, Part B which recently concluded and remained blinded through week 26, and Part C, which contains an open-label treatment part from week 26 to 52.

The COMP005 trial was a randomized, double-blind, placebo-controlled study, which enrolled 258 participants across the United States 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). There was a potential for a total of 3 doses of COMP360 across a 52-week period. The trial was comprised of three parts: Part A, which was blinded through 6 weeks; Part B, which was blinded through week 26; and Part C, which had 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[4]. 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.

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 regarding the safety or efficacy of our investigational COMP360 psilocybin treatment, including as a treatment for TRD and its potential impact on patients’ lives the potential for COMP360 to change the treatment landscape for depression; any implication that these topline results will be predictive of full safety and efficacy data from our phase 3 program; our plans and expectations regarding our clinical trials; our expectations regarding the timing of our rolling submission of a new drug application, or NDA, for COMP360 psilocybin treatment in TRD and the timing of the review by the Food and Drug Administration, or FDA, of such NDA, including potential acceleration due to the grant of rolling review and award of a National Priority Voucher for COMP360 psilocybin treatment in TRD; the potential for the pivotal phase 3 program in TRD to support regulatory filings and approvals on an accelerated basis or at all; our expectations regarding potential

commercial launch timelines and our commercial readiness; our efforts and our ability to obtain regulatory approval and adequate coverage and reimbursement; and our expectations regarding the benefits of our investigational COMP360 psilocybin treatment, including as a treatment of TRD or PTSD. 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 topline results; 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; that the rolling review process and/or the National Priority Voucher pilot program may not actually lead to a faster FDA review or approval process; our efforts to obtain FDA approval, or approval from regulatory authorities in other jurisdictions, for our investigational COMP360 psilocybin treatment on an accelerated basis, or at all, may be unsuccessful; the timing and substance of decisions by the Drug Enforcement Administration and states to reschedule COMP360 psilocybin treatment, if approved by FDA, which contains Schedule I controlled substances and must be rescheduled before commercializing COMP360 psilocybin in the U.S., may not be favorable; 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.

References

1. Montgomery-Åsberg Depression Rating Scale
2. Responder: ≥50% decrease in total score from baseline
3. Remitter: ≤12 MADRS total score and no single item ≥4
4. Wing V, et al. Poster S97 Contemporary Estimate of the National Prevalence of Treatment-Resistant Depression in the United States. Presented at ADAA 2026

Enquiries

Media: Dana Sultan-Rothman, media@compasspathways.com
Investors: Stephen Schultz, stephen.schultz@compasspathways.com, +1 401 290 7324

Source: Compass Pathfinder Limited

Figure 1: 25 mg participants who continued through Part C

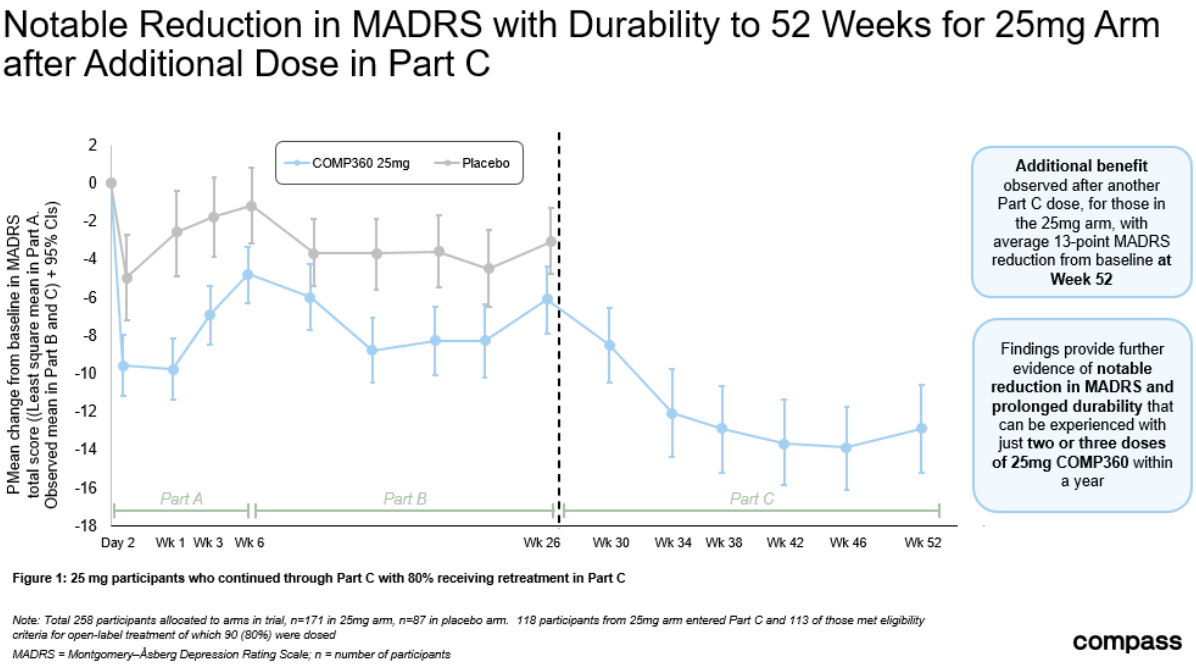

Figure 1: 25 mg participants who continued through Part C with 80% receiving retreatment in Part C

Note: Total 258 participants allocated to arms in trial, n=171 in 25mg arm, n=87 in placebo arm. 118 participants from 25mg arm entered Part C and 113 of those met eligibility criteria for open-label treatment of which 90 (80%) were dosed

MADRS = Montgomery–Åsberg Depression Rating Scale; n = number of participants

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Figure 2: Placebo participants who continued through Part C

Part C Placebo Arm data Further Reinforces COMP360 Profile of Rapid Onset, Meaningful Effect and Durability with a Single Dose

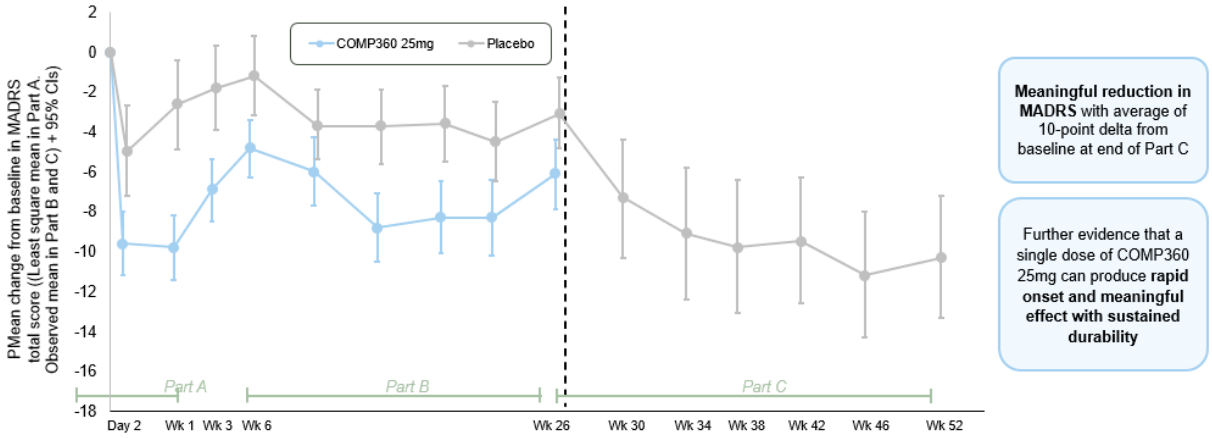

Figure 2: Placebo participants who continued through Part C with 90% receiving their first dose of COMP360 25mg in Part C

Note: Total 258 participants allocated to arms in trial, n=171 to 25mg arm, n=87 to placebo arm. 61 participants from Placebo arm entered Part C and 58 of those met eligibility criteria for open-label treatment of which 52 (90%) were dosed

MADRS = Montgomery–Åsberg Depression Rating Scale; n = number of participants

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Figure 3: Response and remission rates post open-label treatment

Strong Response and Remission Rates in Open-Label Part C

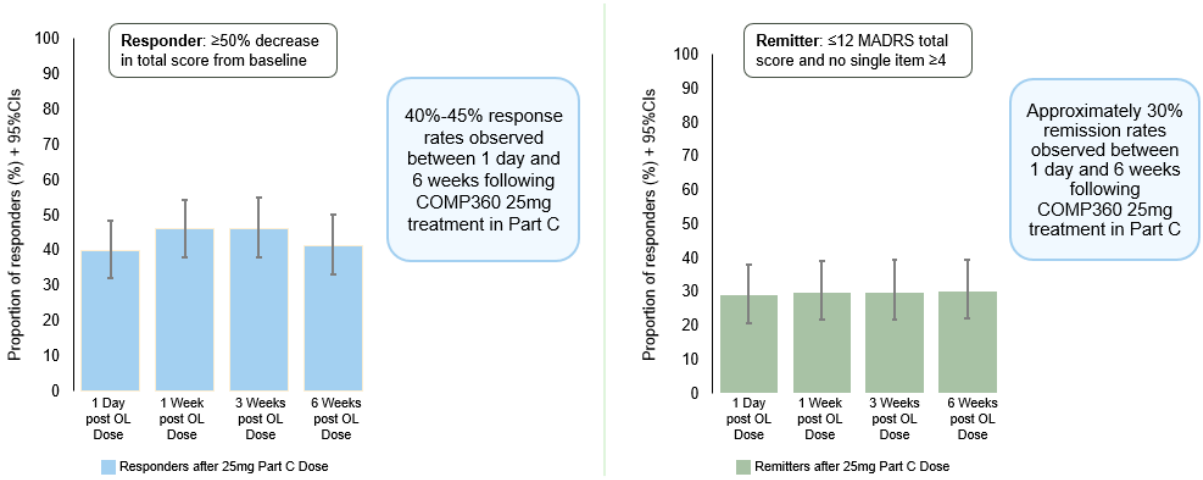

Figure 3: Response and remission rates post open-label treatment for all participants who received a 25mg dose in Part C

Note: Response/remission rates based on the 142 participants (n=90 from 25mg arm, n=52 from original Placebo arm) who received a 25mg dose in Part C. Percentages are based on the number of observed participants at the visit

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