



NEWS RELEASE

Compass Pathways Commends White House Executive Order to Accelerate Research and Access for Psychedelic Treatments

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LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to accelerating patient access to evidence-based innovation, welcomes the White House Executive Order on accelerating medical treatments for serious mental illness.

"We commend the Administration's Executive Order on psychedelic treatment which recognizes the profound urgency of the mental health crisis facing millions of Americans and the potential impact FDA-approved psychedelics could have," said Kabir Nath, CEO at Compass Pathways. "Today's announcement aligns regulatory urgency with patient need, and we applaud the Administration for taking this important step forward in accelerating access, without compromising rigorous science. Compass is conducting the largest, most robust classic psychedelic studies to date with COMP360 synthetic psilocybin. We have recently reported two positive phase 3 trials in treatment-resistant depression (TRD) with highly statistically significant and clinically meaningful data that demonstrates effects within one day and durability lasting at least through 6 months after just one or two doses for those who have a clinically meaningful response, as well as a generally well-tolerated and safe profile. We are already actively working with the FDA on a rolling submission and review for COMP360 in TRD and look forward to continuing our efforts to bring this potential transformative treatment to the millions of Americans in need."

Nath continued, "An estimated four million Americans are living with TRD and 13 million with PTSD - two conditions that have seen critically limited innovation for decades and where we have late-stage clinical programs underway, as well as ongoing work with the VA. With today's Executive Order including the potential for accelerated regulatory and rescheduling processes, should COMP360 be approved, we will be ready to make this treatment available to patients."



COMP360's transformative clinical profile

COMP360 is the first classic psychedelic¹ to consistently achieve a highly statistically significant result and clinically meaningful effect in two phase 3 studies, with a generally well-tolerated and safe profile. With data generated across more than 1,000 participants living with treatment-resistant depression, COMP360's transformative clinical profile is redefining rapidity and durability for TRD patients. Unlike any other approved treatment available for this patient population today, COMP360 may demonstrate effects as quickly as within one day with durability lasting at least through 6 months, after only one or two doses, for those who achieve a clinically meaningful response. With respect to COMP360's safety profile, a significant majority of treatment-emergent adverse events (TEAEs) are mild or moderate in severity, and the vast majority resolve within 24 hours. Based on this data, we are actively working with the FDA on a rolling submission and review for COMP360 in TRD.

Compass also continues to chart the path forward for patients living with PTSD. After receiving clearance for their IND in this indication, the Company is starting a late-stage trial.

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 expectations 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 or PTSD; our plans and expectations regarding our clinical trials, including our ongoing phase 3 trials in TRD and our phase 2b/3 trial in PTSD; our expectations regarding discussions with the FDA, including discussions regarding 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 efforts and 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 acceleration strategies for our NDA submission may not be successful; FDA ultimately 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; 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, the prospectus supplement related to the proposed public offering we plan to file 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

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