NEWS RELEASE

Compass Pathways Announces FDA Granted NDA Rolling Review Request and Awarded Commissioner's National Priority Voucher

2026-04-24

- Compass is the most advanced company in classic psychedelics and has generated positive data from two ongoing large, well controlled Phase 3 clinical trials, designed to uphold the highest regulatory standards
- FDA grants Compass NDA rolling submission and review request, based on Phase 3 data
- CNPV awarded for COMP360, Compass' proprietary formulation of synthetic psilocybin, for treatment-resistant depression (TRD)
- CNPV further accelerates momentum and Compass is confident and ready to deliver for patients

LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health, today announced the U.S. Food and Drug Administration (FDA) granted Compass NDA rolling review request and selected COMP360, Compass' proprietary formulation of synthetic psilocybin, for the Commissioner's National Priority Voucher (CNPV) program for treatment-resistant depression (TRD). Companies selected for the voucher program will be entitled to benefits including enhanced communications and a shortened 1-2 month review time following filing of a New Drug Application (NDA), while maintaining FDA's rigorous safety and efficacy standards.

"We are honored and grateful to be selected for the CNPV which is a clear validation of both the urgent unmet need facing millions of people living with treatment resistant depression and the innovative science of COMP360," said Kabir Nath, Chief Executive Officer of Compass Pathways. "As the most advanced company in the classic psychedelics field, Compass has generated positive data from two large, well controlled Phase 3 clinical trials. Based on the strength of our data, the FDA granted us a rolling NDA submission and review. Importantly, while the CNPV

may provide process efficiencies and accelerated review timelines, an NDA submission must still meet FDA's established standards of clinical evidence, scientific rigor, and regulatory compliance. We are confident we meet these standards."

Nath continued, "Patients with TRD often endure years of persistent suffering with limited options, and the need for meaningful innovation for these patients has never been more urgent. We are well advanced in our commercial preparations and the CNPV could further accelerate momentum toward bringing our transformative treatment, if approved, to patients who have been waiting far too long."

COMP360's transformative clinical profile

COMP360 is the first classic psychedelic[1] 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 TRD, 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 after administration with durability lasting at least through 6 months for those who achieve a clinically meaningful response after one or two doses. 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.

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[2]. **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 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; any implication that past results will be predictive of future results; 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 the potential benefits of being selected for Commissioner's National Priority Voucher pilot program, including without limitation, reduced review timelines following submission of a new drug application; 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; that the full results and safety data from our Phase 3 clinical trials in TRD may not be consistent with the preliminary results to date; that the Commissioner's National Priority Voucher pilot program may not actually lead to a faster FDA review or approval process; that the Commissioner's National Priority Voucher pilot program does not change the safety and efficacy standards for approval or the quality of evidence necessary to support approval of COMP360 and our efforts to obtain FDA approval, or approval from regulatory authorities in other jurisdictions, for our investigational COMP360 psilocybin treatment may be unsuccessful; that 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' 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' 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. Wing V, et al. Contemporary Estimate of the National Prevalence of Treatment-Resistant Depression in the United States. ADAA Annual Meeting 2026, April 9 – 11, Chicago, IL.

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Source: Compass Pathfinder Limited