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COMPASS news

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COMP360 psilocybin therapy shows potential in exploratory open-label studies for anorexia nervosa and severe treatment-resistant depression



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Positive early signals seen in two investigator-initiated studies presented at the Society of Biological Psychiatry Annual Meeting in New Orleans

COMPASS Pathways plc (Nasdaq: CMPS) ("COMPASS"), a mental health care company dedicated to accelerating patient access to evidence-based innovation in mental health, today announced that positive data demonstrating the potential of COMP360 psilocybin therapy in anorexia nervosa and severe treatment-resistant depression has been presented at the Society of Biological Psychiatry Annual Meeting in New Orleans, from two investigator-initiated studies.

The first study looked at the safety and efficacy of COMP360 psilocybin therapy in patients with severe treatment-resistant depression (n=12), with a single 25mg dose, and was run by Dr Scott Aaronson at Sheppard Pratt, Baltimore. All participants had tried at least five antidepressant treatments without success, prior to joining the study. The researchers found that 58.3% (n=7) of the participants had maintained response criteria, for the Montgomery-Asberg Depression Rating Scale (MADRS) at 12 weeks after COMP360 psilocybin



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administration, and a quarter had maintained remission (n=3). There was no increase in the suicidality score based on the MADRS, and no serious adverse events were reported throughout the study. The data was presented at the conference on poster F120*.

The second study investigated the safety, efficacy, and tolerability of COMP360 psilocybin therapy in patients with anorexia nervosa (n=10), with a single 25mg dose, and was conducted by Dr Walter Kaye at the University of California San Diego School of Medicine. 30% (n=3) of participants experienced clinically significant reductions in eating disorder psychopathology at the 1-month follow up, and 40% (n=4) experienced clinically significant reductions at the 3-month follow-up. Participants demonstrated statistically significant reductions in shape concerns at the 1-month follow-up (p<.05), and statistically significant reductions in eating concerns at the 3-month follow-up (p<.05). Changes in weight concerns were approaching statistical significance. COMP360 psilocybin therapy was well-tolerated and 90% of participants found the experience to be meaningful and therapeutic. No serious adverse events were reported. The data was presented at the conference on poster T142**.

Dr Guy Goodwin, Chief Medical Officer, COMPASS Pathways, said, "These independent studies looked at two of the most challenging mental health conditions, where patients are unlikely to receive relief from current available treatments. The results provide promising preliminary evidence that COMP360 psilocybin therapy could help people living with anorexia nervosa and severe treatment-resistant depression and underlines our belief that this needs to be further investigated in larger scale clinical studies."

*An Open Label Study of the Safety and Efficacy of COMP360 in Participants With Severe Treatment-Resistant Depression (P-TRD); Scott T. Aaronson, M.D., Tammy Miller, PsyD., MacKenzie Forbes, M.S., Samuel Rudow B.S., and Audrey Shoultz, B.S. Sheppard Pratt, Baltimore, Maryland; Trisha Suppes, M.D., PhD., Stanford University School of Medicine, VA Palo Alto Health Care System, Palo Alto, CA 94304

**The Safety, Efficacy, and Tolerability of Psilocybin in Participants with Anorexia Nervosa; Stephanie Knatz Peck PhD, Samantha Shao BS, Susan Murray PhD, Walter H. Kaye MD, University of California San Diego School of Medicine, Department of Psychiatry

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About COMPASS Pathways

COMPASS Pathways plc (Nasdaq: CMPS) is a mental health care company dedicated to accelerating patient access to evidence-based innovation in mental health. Our focus is on improving the lives of those who are suffering with mental health challenges and who are not helped by current treatments. We are pioneering the development of a new model of psilocybin therapy, in which our proprietary formulation of synthetic psilocybin, COMP360, is administered in conjunction with psychological support. COMP360 has been designated a



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Breakthrough Therapy by the US Food and Drug Administration (FDA), for treatment-resistant depression (TRD), and we have completed a Phase IIb clinical trial of psilocybin therapy for TRD, in 22 sites across Europe and North America. This was the largest randomised, controlled, double-blind psilocybin therapy clinical trial ever conducted, and our topline data showed a statistically significant ($p < 0.001$) and clinically relevant improvement in depressive symptom severity after three weeks for patients who received a single high dose of COMP360 psilocybin with psychological support. We are also running a phase II clinical trial of COMP360 psilocybin therapy for post-traumatic stress disorder (PTSD). 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.
www.compasspathways.com (<http://www.compasspathways.com>)

Availability of other information about COMPASS Pathways

Investors and others should note that we communicate with our investors and the public using our website (www.compasspathways.com), our investor relations website (ir.compasspathways.com), and on social media (LinkedIn), including but not limited to investor presentations and investor fact sheets, US Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in us to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include additional social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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, the safety or efficacy of COMP360 psilocybin therapy as a treatment for depression, COMPASS's business strategy and goals, including its ability to



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launch and commercialise products, COMPASS's ability to continue to advance its research or develop plans to bring its product candidates to patients, including COMP360, and COMPASS's expectations regarding the benefits of its psilocybin therapy. 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: preclinical research and clinical development is lengthy and uncertain, and therefore our preclinical studies and clinical trials may be delayed or terminated, or may never advance to or in the clinic; and those risks and uncertainties described under the heading "Risk Factors" in COMPASS's annual report on Form 10-K filed with the US Securities and Exchange Commission (SEC) on 24 February 2022 and in subsequent filings made by COMPASS with the 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.

Enquiries

Media: Amy Lawrence, amy@compasspathways.com, +44 7813 777 919

Investors: Stephen Schultz, stephen.schultz@compasspathways.com, +1 401 290 7324



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