



Study results of psilocybin treatment in bipolar II depression published in JAMA Psychiatry

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Believed to be first ever psilocybin clinical trial for treatment of bipolar II depression

LONDON, Dec. 06, 2023 (GLOBE NEWSWIRE) -- Compass Pathways plc (Nasdaq: CMPS) ("Compass"), a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health, today announced the publication of a paper in [JAMA Psychiatry](#) that demonstrates the potential for investigational COMP360 psilocybin treatment in treatment-resistant bipolar type II disorder (bipolar II). Results from the investigator-initiated open-label study were first presented at the Annual Meeting of the American College of Neuropsychopharmacology in 2022.

The study, which was conducted by Dr Scott Aaronson at Sheppard Pratt, Baltimore, and funded by Compass, investigated the safety and efficacy of a single 25mg dose of COMP360 psilocybin treatment in participants with treatment-resistant bipolar II. The primary endpoint was change in Montgomery-Åsberg Depression Rating Scale (MADRS) total score from baseline to week 3. All participants (n = 15) had lower MADRS scores with a mean change from baseline of -24.0 points at week 3, 12 participants met the response criteria and 11 met the remission criteria.

There was no increase in the suicidality score based on the MADRS, no manic symptoms and no unexpected adverse events or difficulties with the dosing sessions reported throughout the study. The most common adverse event was headache reported by 4 out of 15 participants on the day of dosing, with symptoms resolving within 24 hours.

"We're pleased that our study has been recognized and published by a highly regarded peer-reviewed journal," said Dr Scott Aaronson, MD, Chief Science Officer, Institute for Advanced Diagnostics and Therapeutics, Sheppard Pratt. "In what we believe to be the first study of its kind, we saw a significant number of patients experience relief from their bipolar II depression symptoms after a single 25mg dose of COMP360 psilocybin treatment. These findings need to be validated in larger studies."

Dr Guy Goodwin, Chief Medical Officer, Compass Pathways, said: "Bipolar II can be extremely difficult-to-treat and if medicines don't provide adequate relief, it can be even more challenging to live with. We are committed to finding solutions for those living with mental illness who have limited or no options, so it's encouraging to see early signals that COMP360 psilocybin may have potential to help those living with the condition."

About Compass Pathways

Compass Pathways plc (Nasdaq: CMPS) is a biotechnology 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 treatment, in which our proprietary formulation of synthetic psilocybin, COMP360, is administered in conjunction with psychological support. COMP360 has been designated a Breakthrough Therapy by 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).

We have commenced a phase 3 clinical program of COMP360 psilocybin treatment in TRD, the largest randomized, controlled, double-blind psilocybin treatment clinical program ever conducted. Previously, we completed a phase 2b study with top line data showing a statistically significant ($p < 0.001$) and clinically relevant improvement in depressive symptom severity after three weeks for patients who received a single 25mg dose of COMP360 psilocybin with psychological support. We are also conducting phase 2 clinical studies of COMP360 psilocybin treatment for post-traumatic stress disorder (PTSD) and anorexia nervosa.

Compass is headquartered in London, UK, with offices in New York and San Francisco in the United States. Our vision is a world of mental wellbeing. 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", "could", "expect", "plan", "believe", "potential", "promise", "signal", "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 investigational COMP360 psilocybin treatment as a treatment for depression or bipolar II depression, the potential for the pivotal phase 3 program or other trials to support regulatory filings and approvals, Compass's business strategy and goals, Compass's ability to continue to advance its research or develop plans to bring COMP360 psilocybin treatment to patients, and Compass's expectations regarding the benefits of its 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: clinical development is lengthy and outcomes are uncertain, and therefore our clinical trials may be delayed or terminated; the results early-stage clinical trials or investigator-initiated studies of our investigational COMP360 psilocybin treatment or any future therapeutic candidates may not be predictive of the results of later stage clinical trials; our efforts to obtain marketing approval from the applicable regulatory authorities in any jurisdiction for COMP360 or any of future product candidates may be unsuccessful; and our efforts to 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.

Enquiries

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

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