



Data Demonstrating Long-Term Improvement in Depression in Cancer Patients Following Single Dose of COMP360 Psilocybin Therapy to be Presented at ASCO 2023

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- *More than half of the patients demonstrated remission of depression at 18 months, after a single dose of 25mg investigational COMP360 psilocybin with psychological support*
- *Open label phase 2 study, conducted by Sunstone Therapies and scheduled to be presented at the ASCO annual meeting on June 5, is believed to be the longest clinical study of psilocybin ever conducted*

LONDON, May 26, 2023 (GLOBE NEWSWIRE) -- 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 new long-term efficacy data of investigational COMP360 psilocybin in cancer patients with major depressive disorder will be presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO).

More than half of the patients (16/28) treated with a single dose of 25mg COMP360 psilocybin with psychological support remained in remission from their depression at 18 months post administration. The investigator-initiated study, led by Manish Agrawal, MD, at [Sunstone Therapies](#), is believed to be the longest study of psilocybin therapy ever conducted.

The trial was a phase 2, single-center, fixed-dose, open-label study in 30 patients with curable and incurable cancer and major depressive disorder. Patients were treated with a single dose of 25mg of COMP360 psilocybin, administered simultaneously in group cohorts of 3-4, with group and individual psychological support, and evaluated at 8 weeks and 18 months. Of 30 patients from the parent study, 28 were enrolled in the follow-up study. Key results:

- 18/28 patients (64.2%) demonstrated sustained clinical response from baseline to 18 months follow-up
- 16/28 patients (57.1%) demonstrated remission of depression at 18 months

The original phase 2 study conducted by Sunstone was completed in 2021 and results were published in [JAMA Oncology](#) in April 2023.

Guy Goodwin, MD, Chief Medical Officer, COMPASS Pathways, said: "This study conducted by Sunstone Therapies is extremely encouraging and demonstrates the potential durability of COMP360 psilocybin therapy. COMPASS Pathways is looking at the long-term effects of COMP360 in our phase 3 programme in treatment-resistant depression."

Manish Agrawal, MD, Chief Executive Officer, Sunstone Therapies, and the trial's Principal Investigator, said: "This pioneering study is the first of its kind, conducted within a community hospital cancer center. The results show significant improvement in these patients' depression symptoms long-term and, if replicated in larger studies, could open the door to a wider and faster adoption of psilocybin therapy in the future."

COMP360 is COMPASS's investigational proprietary formulation of synthetic psilocybin, administered in conjunction with psychological support. COMPASS is currently conducting a phase 3 clinical program of COMP360 psilocybin therapy in treatment-resistant depression (TRD), the largest of its kind ever conducted. This program follows positive results from COMPASS's phase 2b study published in the [New England Journal of Medicine](#).

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 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 COMP 360 psilocybin therapy in TRD, the largest randomized, controlled, double-blind psilocybin therapy 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 high dose of COMP360 psilocybin with psychological support. We are also conducting phase 2 clinical studies of COMP360 psilocybin therapy 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”, “might”, “will”, “could”, “should”, “expect”, “intend”, “plan”, “anticipate”, “believe”, “estimate”, “predict”, “possible”, “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 its investigational COMP360 psilocybin therapy, including for treatment of TRD, anorexia nervosa, PTSD, and major depressive disorder, COMPASS’s expectations regarding its ongoing preclinical work and clinical trials and development efforts and COMPASS’s expectations regarding investigator-initiated studies of its investigational COMP360 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: clinical development is lengthy and outcomes are uncertain, and therefore our clinical trials may be delayed or terminated; the possibility of unfavorable results from additional clinical trials of COMP360 psilocybin therapy or from subsequent analysis of existing data or new data received from additional ongoing and future studies of COMP360 psilocybin therapy; 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 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.

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