

Compass Pathways announces investigational COMP360 psilocybin treatment was well-tolerated in phase 2 study of post-traumatic stress disorder

2023-12-19

Initial safety findings at 24 hours post dosing were consistent with studies of COMP360 in other psychiatric conditions

LONDON, Dec. 19, 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 that an initial data readout showed that investigational COMP360 psilocybin treatment was well-tolerated in a phase 2 clinical trial of people living with post-traumatic stress disorder (PTSD). This is believed to be the first study reporting on the feasibility of psilocybin as a potential treatment for PTSD.

The open-label study evaluated the safety and tolerability of COMP360 psilocybin treatment in patients with PTSD as a result of trauma experienced as adults. 22 participants received a single 25mg dose of investigational COMP360 psilocybin treatment. The initial data readout, based on monitoring patients at 24 hours post COMP360 administration, indicated that COMP360 was well-tolerated and the safety profile was as expected, with no treatment emergent serious adverse events recorded.

In line with the study design, participants are being monitored for a 12-week period post dosing. Safety and efficacy data over that period are expected to be announced in spring 2024. The study is being conducted in the UK and US at The Institute of Psychiatry, Psychology & Neuroscience at King's College London, Icahn School of Medicine at Mount Sinai, New York City and Sunstone Therapies, Rockville, Maryland.

Dr Guy Goodwin, Chief Medical Officer, Compass Pathways, said: "Safety is of paramount importance when developing potential new treatments, so we are pleased to see these positive safety signals. These results are

consistent with findings from other studies and add to the growing body of evidence to demonstrate the potential of COMP360 in difficult-to-treat mental health conditions.”

Dr James Rucker, Consultant Psychiatrist and Lead of the Psychoactive Trials Group at King’s College London, said: “PTSD is a very distressing condition and existing treatments are not always effective. It’s encouraging to see these initial safety results for COMP360 psilocybin treatment in this patient population and we look forward to a more detailed analysis of the study next year.”

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”, “will”, “could”, “would”, “expect”, “intend”, “plan”, “anticipate”, “believe”, “potential” and “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, post-traumatic stress disorder or anorexia nervosa, 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, obtain regulatory approval 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: full results from this phase 2 study in post-traumatic stress disorder or results from future studies may not be consistent with the preliminary results to date, clinical development is lengthy and outcomes are uncertain, and therefore our clinical trials may be delayed or terminated; the results early-stage clinical trials of our investigational COMP360 psilocybin treatment 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