First clinical study results of psilocybin treatment in anorexia nervosa published in Nature Medicine

July 25, 2023

COMP360 psilocybin treatment shows potential in exploratory open-label investigator-initiated study in anorexia nervosa

LONDON, July 25, 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 *Nature Medicine* that demonstrates the potential for COMP360 psilocybin treatment in anorexia nervosa. The investigator-initiated open-label study was conducted by Drs. Walter Kaye and Stephanie Knatz Peck at the University of California San Diego School of Medicine and is believed to be the first clinical research study to report the effects of psilocybin treatment in anorexia nervosa.

The study investigated the safety, efficacy, and tolerability of a single 25mg dose of COMP360 psilocybin, with psychological support (referred to as "psilocybin therapy" in the paper), in female patients with anorexia nervosa (n=10). The results showed:

- 40% (n=4) of participants experienced clinically significant reductions in eating disorder psychopathology at the three-month follow-up.
- Participants demonstrated statistically significant reductions from baseline in shape concerns at the one-month follow-up ($p<0.05$), and weight concerns ($P = 0.04$, $d = 0.78$) at the three-month follow-up. Changes in eating concern were approaching significance at three-month follow-up ($P = 0.051$, $d = 0.71$).
- Five participants demonstrated an increase in body mass index (BMI) at three-month follow-up (range, 0.4–1.2 kg/m2). Changes in BMI were not statistically significant.
- Overall, the psilocybin experience was regarded as meaningful by participants. Ninety percent endorsed feeling more positive about life endeavors; 80% endorsed the experience as one of the top five most meaningful of their life; and 70% reported experiencing a shift in personal identity and overall quality of life.
- COMP360 psilocybin treatment was well tolerated. All adverse events were mild and transient in nature (the most common being headache, fatigue and nausea). No serious adverse events were reported.

The data were first presented at the Society of Biological Psychiatry Annual Meeting in New Orleans in 2022.

Dr. Guy Goodwin, Chief Medical Officer at COMPASS Pathways, said, “People living with anorexia nervosa urgently need new options. This study shows promising preliminary evidence that COMP360 psilocybin treatment could help people living with this difficult-to-treat condition. We are now looking to investigate these findings further in our larger phase 2 study.”

Dr. Kaye added, “Anorexia nervosa is one of biggest challenges we face in psychiatry, since there is a high risk of dying from suicide or other causes. We’re pleased to have conducted one of the first studies of psilocybin treatment in anorexia nervosa, and for our study to be published in one of the world’s leading peer-reviewed publications. We hope our preliminary research proves to be an important step in finding new and better options for patients with this difficult-to-treat condition.”

Dr. Knatz Peck concluded, “There are no proven treatments to reverse core symptoms in anorexia and even after or in spite of weight stabilization, people with anorexia often continue to suffer with debilitating psychological symptoms that place them at risk for relapse and life impairment. Our findings suggest that a subset of people experienced significant improvements in eating disorder psychopathology. Our hope is that this study provides a pathway to continue to find better ways to address the psychology of anorexia from the inside out.”

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 COMP 360 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 “aim”, “may”, “might”, “will”, “could”, “should”, “expect”, “intend”, “plan”, “hope”, “believe”, “predict”, “possible”, “potential”, “promise”, “suggest”, “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 treatment, including for treatment of anorexia nervosa, TRD and other mental health conditions, COMPASS’s expectations regarding its ongoing phase 2 trial in anorexia nervosa and COMPASS’s expectations regarding its ongoing pivotal phase 3 program in TRD and the potential for its phase 3 program or other trials to support regulatory filings and approvals. 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 treatment or from subsequent analysis of existing data or new data received from additional ongoing and future studies of COMP360 psilocybin treatment; 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.

Enquiries

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

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