



COMPASS Pathways launches phase II clinical trial of psilocybin therapy in anorexia nervosa

July 28, 2022

Multi-centre, double-blind randomised controlled phase II trial will investigate the efficacy of COMP360 psilocybin therapy in anorexia nervosa for which there is currently no approved pharmacological treatment option

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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 it has launched a multi-centre, double-blind randomised controlled phase II clinical trial investigating the efficacy of COMP360 psilocybin, administered with psychological support, in people with anorexia nervosa.

The phase II clinical trial will compare the effects of 25 mg and 1 mg of investigational COMP360 psilocybin when administered with psychological support, in 60 participants with anorexia nervosa, across four world-leading research institutes in the UK and US (King's College London, Columbia University Irving Medical Center, University of California San Diego School of Medicine and Sheppard Pratt). Any changes in symptoms after COMP360 psilocybin therapy will be measured using the Eating Disorder Examination (EDE) interview and other measures; the trial primary endpoint is change from baseline in the EDE global score at week 4 after administration of COMP360 psilocybin therapy.

Anorexia nervosa is a serious mental illness characterised by severe restriction of calorie intake and a preoccupation with weight and shape. Anorexia carries the highest mortality rate (5.86)¹ of all psychiatric disorders because of medical complications and suicide;² approximately 20-40% of deaths in anorexia nervosa are thought to result from suicide.³ Currently there are no approved pharmacological treatments. Globally, about 2.2% of women and 0.3% of men suffer from anorexia nervosa at some point in their lives.⁴

In May, COMPASS announced positive early signals from an exploratory, open-label investigator-initiated [study](#) conducted by Dr Walter Kaye, Professor of Psychiatry at the University of California San Diego School of Medicine Department of Psychiatry Eating Disorders Program and Principal Investigator on the phase II trial.⁵ Dr Kaye said: "Anorexia nervosa is one of the most difficult to treat conditions we face in psychiatry, with the highest suicide rate of any mental health challenge. Not only can it have a huge impact on the people living with it, but also on the people closest to them. Research and progress are urgently needed; we've already seen encouraging data from an exploratory, open-label study in treating anorexia nervosa with COMP360 psilocybin therapy, and this phase II study represents another important step forward."

Dr Guy Goodwin, Chief Medical Officer, COMPASS Pathways, said, "There are no approved pharmacological treatment options for people living with anorexia nervosa, and we are determined to change this. We are conducting this rigorous clinical trial to understand whether COMP360 psilocybin, with psychological support, could help people living with anorexia nervosa who urgently need new options."

This will be the first study to use myPathfinder, COMPASS' digital application for supporting patients throughout their COMP360 psilocybin therapy journey. The app is optional for participants in the study, providing engaging education about the therapy model, and with participant consent, collecting real-world data for research on treatment responsiveness. Learn more [here](#).

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About anorexia nervosa

Anorexia nervosa is a serious mental illness characterised by severe restriction of calorie intake and a preoccupation with weight and shape. It carries the highest mortality rate of all psychiatric disorders.² This high mortality rate is explained in part by the physical complications (muscle and bone problems, such as osteoporosis; damage to the brain leading to seizures and memory issues; and heart problems including heart failure) and in part by an increased rate of suicide; approximately 20-40% of deaths in anorexia nervosa are thought to result from suicide.³ Globally, about 2.2% of women and 0.3% of men suffer from anorexia nervosa at some point in their lives.⁴

About the COMP360 psilocybin therapy phase II study (COMP401)

The study will recruit 60 participants who currently meet the criteria for either the restrictive or binge-purge subtypes of anorexia nervosa (mild to severe), with a history of disordered eating of at least three years before entering the study and have tried at least one previous treatment in the past three years.

Participants will be randomised in a 2:1 ratio to receive single administration session with either COMP360 25 mg or COMP360 1 mg. Participants will be followed regularly for a period of 12 weeks. During these visits, measures of changes in their psychological symptoms (via structured interviews and self-reported questionnaire) and physical symptoms (via weight measurement) of anorexia nervosa will be performed. Safety assessments will

also be carried out to monitor physical and laboratory values and suicidality.

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 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

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, anorexia nervosa or any other disease, COMPASS’s business strategy and goals, including its ability to obtain regulatory approval of its product candidates, including COMP360, and to 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 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, 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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References:

- ¹ Mortality rates in patients with anorexia nervosa and other eating disorders. A meta-analysis of 36 studies; Jon Arcelus, Alex J Mitchell, Jackie Wales, Søren Nielsen. Archives of General Psychiatry. <https://pubmed.ncbi.nlm.nih.gov/21727255/>. Last accessed: July 2022.
- ² Rethinking Therapeutic Strategies for Anorexia Nervosa: Insights From Psychedelic Medicine and Animal Models; Claire J. Foldi, Paul Liknaitzky, Martin Williams, Brian J. Oldfield. Frontiers in Neuroscience. <https://www.frontiersin.org/articles/10.3389/fnins.2020.00043/full>. Last accessed: July 2022
- ³ Characteristics of Suicide Attempts in Anorexia and Bulimia Nervosa: A Case–Control Study; Sébastien Guillaume, Isabelle Jaussent, Emilie Olié, Catherine Genty, Jacques Bringer, Philippe Courtet, Ulrike Schmidt. PLOS ONE. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0023578>. Last accessed: July 2022
- ⁴ Epidemiology of eating disorders: An update; Anna Keski-Rahkonen, Anu Raevuori, Hans Wijbrand Hoek. https://www.researchgate.net/publication/252793579_Epidemiology_of_eating_disorders_An_update. Last accessed: July 2022.
- ⁵ 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.

Videos accompanying this announcement are available at:

<https://www.youtube.com/embed/U3Pp4UQunTo>

<https://www.youtube.com/embed/1m7srY8HXEM>

<https://www.youtube.com/embed/BUK3RgixmpA>