



COMPASS Pathways Announces Phase 3 Pivotal Program Design for COMP360 in Treatment Resistant Depression at Capital Markets Day

October 12, 2022

First ever phase 3 program of psilocybin therapy globally scheduled to begin in 2022

LONDON, Oct. 12, 2022 (GLOBE NEWSWIRE) -- COMPASS Pathways plc (Nasdaq: CMPS), a mental health care company dedicated to accelerating patient access to evidence-based innovation in mental health, today announced the Phase 3 pivotal program design for COMP360 psilocybin therapy in treatment resistant depression (TRD) during a virtual Capital Markets Day. The session, attended by members of COMPASS Pathways' executive leadership and key opinion leaders, included a review of the TRD treatment landscape as well as COMPASS' clinical care and digital strategy, patient/market access and commercial model, and broader development pipeline (recording available [here](#)).

COMPASS' program will be the first ever Phase 3 program of psilocybin therapy globally, and follows positive results from its Phase 2b study in treatment-resistant depression, [presented at the American Psychiatric Association annual meeting in May 2022](#). The Phase 3 program is composed of three clinical trials, two pivotal trials and one long-term follow-up, and is expected to commence by the end of 2022. The pivotal program design is as follows:

- Pivotal trial 1 (COMP 005) (n=378): a single dose (25mg) monotherapy compared with placebo. This trial is designed to replicate the treatment response seen in the Company's Phase 2b study (n=233).
- Pivotal trial 2 (COMP 006) (n= 568): a fixed repeat dose monotherapy using three dose arms: 25mg, 10mg and 1mg. This trial is designed to investigate if a second dose can increase the number of responders and/or improve response seen in the Company's Phase 2b study and explore the potential for a meaningful treatment response from repeat administration of COMP360 10mg.
- The primary endpoint in both pivotal trials is the change from baseline in MADRS total score at Week 6.

COMPASS Pathways' Capital Markets Day featured the following speakers and topics:

Setting the Scene

George Goldsmith: Welcome and introduction to COMPASS

Kabir Nath: Introduction and agenda for the event

Charlie Nemeroff, [MD, PhD](#), The University of Texas at Austin, Dell Medical School: New horizons in neuropsychiatry

TRD and COMPASS' Phase 3 Program

[John Rush, MD](#), Duke University School of Medicine: TRD patient profile review

Guy Goodwin, MD/Trevor Mill: Phase 3 program and pivotal trial design

[Sidney Zisook, MD](#), University of California, San Diego: Perspective on the COMPASS Phase 3 development program

COMP360 Psilocybin Therapy Delivery and Commercialization

Ekaterina Malievskaia, MD & Greg Ryslik: Clinical care innovation and digital tools

Marco Mohwinkel & Steve Levine, MD: Patient/market access and commercial model

Phyllis Foxworth, Depression and Bipolar Support Alliance: Patient perspective on living with TRD and psilocybin therapy

Beyond TRD

Guy Goodwin, MD: COMPASS' Phase 2 study in PTSD and IIS review

[Walter Kaye, MD](#), University of California, San Diego: Unmet need and current treatment paradigm in Anorexia Nervosa

Guy Goodwin, MD: COMPASS' Phase 2 study in Anorexia Nervosa

Closing Remarks

Kabir Nath: Closing remarks

The virtual event was held on October 12 at 8:00 am ET (1 pm UK). The webcast replay is available [here](#).

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 phase II clinical trials 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 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”, “plan”, “believe”, “estimate”, “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, COMPASS’s strategic plans or objectives, COMPASS’s plans and expected timing for its phase III program in treatment resistant depression and the potential for that or other trials to support regulatory filings and approvals, the future accessibility of COMP360 psilocybin therapy, COMPASS’s ability to launch and successfully commercial COMP360 psilocybin therapy, potential revenue streams if COMP360 psilocybin therapy is approved and COMPASS’s ability to advance COMP360 psilocybin therapy in other areas of high unmet mental health need and to discover and advance new drug compounds. 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 (“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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