



COMPASS Pathways announces publication of positive data from treatment-resistant depression phase 2 clinical trial of COMP360 psilocybin alongside antidepressants in Nature journal, Neuropsychopharmacology

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- Results of COMPASS Pathways' open-label study of COMP360 psilocybin treatment, alongside SSRI antidepressants, suggest that SSRIs do not interfere with the potential therapeutic effect of COMP360

LONDON, July 17, 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 positive data from an open-label phase 2 clinical trial of investigational COMP360 psilocybin in addition to daily selective serotonin reuptake inhibitors (SSRIs) in treatment-resistant depression has been published online in the peer reviewed Nature journal, [Neuropsychopharmacology](#).

The exploratory phase 2 clinical trial used an open-label, fixed-dose design to investigate the safety and efficacy of a single dose of 25mg of COMP360 psilocybin with psychological support, in addition to an SSRI, in 19 participants experiencing treatment-resistant depression. The findings were [first announced](#) in December 2021.

Results:

- Response (a greater than 50% reduction from baseline in MADRS total score¹) and remission (MADRS total score of 10 or less) was seen in 42% of participants at week three.
- The efficacy findings were similar to those from [COMPASS's Phase 2b study](#) of 25mg of COMP360 psilocybin in treatment-resistant depression, where patients were withdrawn from their antidepressants prior to receiving COMP360 (42% response and remission rates at week three versus 37% and 29%, respectively).
- COMP360 psilocybin treatment was generally well tolerated. The most common treatment emergent adverse event was headache. No serious adverse events were reported.

Dr. Guy Goodwin, Chief Medical Officer at COMPASS Pathways, said, "It has long been thought that SSRIs could interfere with the potential therapeutic effect of psilocybin. This data is exciting because it provides a preliminary signal that this is not the case, and that patients could remain on their SSRI antidepressant medication and experience the same effect from COMP360 psilocybin treatment as people who are not on SSRIs."

Goodwin continued, "This could have important clinical implications for patient choice, if COMP360 psilocybin treatment receives regulatory approval for treatment-resistant depression. Withdrawing from antidepressants can be unwelcome for some patients, so the possibility of having the choice to remain on their antidepressant could eventually make COMP360 psilocybin treatment more accessible."

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 treatment in treatment-resistant depression, the largest of its kind ever conducted. This program follows positive results from COMPASS's phase 2b trial published in the [New England Journal of Medicine](#).

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”, “might”, “will”, “could”, “should”, “expect”, “intend”, “plan”, “believe”, “estimate”, “predict”, “possible”, “potential” 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 TRD, anorexia nervosa, and PTSD, COMPASS's expectations regarding its ongoing preclinical work and clinical trials and development efforts, the potential for COMPASS's pivotal phase 3 program or other trials to support regulatory filings and approvals and COMPASS's expectations regarding the benefits of its 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: 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, our efforts to obtain coverage and reimbursement for our investigational COMP360 psilocybin therapy, 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.

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¹ [\[1\]](#) MADRS = Montgomery-Åsberg Depression Rating Scale; response = ≥50% decrease in MADRS total score from baseline; remission = MADRS total score ≤10