



COMPASS Pathways and Kings College London publish cognition results from COMP360 psilocybin study in healthy volunteers

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LONDON, June 03, 2021 (GLOBE NEWSWIRE) -- COMPASS Pathways plc (Nasdaq: CMPS) ("COMPASS"), a mental health care company dedicated to accelerating patient access to evidence-based innovation in mental health, has reported further results from a phase I study showing that its COMP360 psilocybin had no clinically-relevant negative effect on cognitive function, when administered to healthy adult volunteers with support from specially trained therapists.

The data ([see poster](#)) from the randomised, double-blind, placebo-controlled, phase I trial conducted at King's College London, will be presented today at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting, by Dr James Rucker, Consultant Psychiatrist and Senior Clinical Lecturer in Psychopharmacology at King's College London's Institute of Psychiatry, Psychology and Neuroscience (IoPPN). Initial results from the study were published in December 2019. The results published today present a more in-depth analysis of cognitive data and showed some trends of positive effects, but these were minor and call for further exploration in clinical populations.

The study looked at the effects of two doses of COMP360 psilocybin (10mg and 25mg) compared with placebo in 89 healthy male and female adult volunteers. The participants were randomised in a 1:1:1 ratio to receive 10mg COMP360 (n=30), 25mg COMP360 (n=30), or placebo (n=29). The drug was administered simultaneously to up to six participants, who all received 1:1 psychological support from trained therapists throughout the session.

Aspects of cognitive function were measured using the gold standard Cambridge Neuropsychological Test Automated Battery (CANTAB), one day prior to COMP360 administration (baseline), and one week and four weeks after administration.

Key results:

- These findings suggest that single doses of COMP360 do not exert clinically-relevant, negative effects in healthy volunteers on the cognitive functions assessed
- On some of the CANTAB measures, there were trends demonstrating, on average, better cognitive performance in the COMP360 groups by week four, compared with baseline. These findings call for further investigation in clinical populations
- The small sample size, and the fact that participants were typically highly educated, limit the generalisability of results
- As reported previously, there were no serious adverse events, and COMP360 psilocybin was found to be generally safe and well-tolerated

Dr Ekaterina Malievskaia, Chief Innovation Officer and Co-founder, COMPASS Pathways, said: "This study is an important part of our clinical development programme of psilocybin therapy for treatment-resistant depression (TRD). The results are encouraging and we are looking forward to reporting data from our phase IIb trial of COMP360 psilocybin therapy for treatment-resistant depression (TRD) later this year."

Dr Rucker said: "This study, the largest randomised placebo-controlled trial of psilocybin to date, found that COMP360 psilocybin had no clinically-relevant negative effect on cognitive function. The results of the study are clinically reassuring and support further development of psilocybin therapy for patients with mental health conditions that have not improved with existing treatments, such as TRD."

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 are currently conducting a phase IIb clinical trial of psilocybin therapy for TRD, in 22 sites across Europe and North America. We are headquartered in London, UK, with offices in New York, US. Our vision is a world of mental wellbeing. www.compasspathways.com

About King's College London

King's College London is one of the top 10 UK universities in the world (QS World University Rankings, 2018/19) and among the oldest in England. King's has more than 31,000 students (including more than 12,800 postgraduates) from some 150 countries worldwide, and some 8,500 staff.

The Institute of Psychiatry, Psychology & Neuroscience (IoPPN) which is the premier centre for mental health and related neurosciences research in Europe. It produces more highly cited outputs (top 1% citations) on mental health than any other centre (SciVal 2019) and on this metric we have risen from 16th (2014) to 4th (2019) in the world for highly cited neuroscience outputs. World-leading research from the IoPPN has made, and continues to make, an impact on how we understand, prevent and treat mental illness and other conditions that affect the brain. [@KingsIoPPN](https://www.kcl.ac.uk/ioppn)

Availability of other information about COMPASS Pathways

Investors and others should note that the Company communicates with its investors and the public using its website (www.compasspathways.com), its

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 posted on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in the Company 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 the Company's website or these channels, or any other website that may be accessed from the 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 profile of COMP360 and the efficacy of COMP360 psilocybin therapy as a treatment for depression, COMPASS's business strategy and goals, COMPASS's ability to continue to advance its research, including COMP360, and COMPASS's expectations regarding the benefits of its COMP360 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 annual report on Form 20-F filed with the US Securities and Exchange Commission (SEC) on 9 March 2021 and in subsequent filings made by COMPASS with the 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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