



COMP360 psilocybin study of 89 healthy participants published in Journal of Psychopharmacology

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Study demonstrates feasibility of simultaneous administration of COMP360 psilocybin in a controlled setting to healthy participants with 1:1 therapist support

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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, shared results today of a phase I study showing the feasibility of administering COMP360 psilocybin to up to six healthy participants simultaneously, with 1:1 support. The study, peer-reviewed and published in *The Journal of Psychopharmacology* as "*The effects of psilocybin on cognitive and emotional functions in healthy participants: results from a phase I, randomised, placebo-controlled trial involving simultaneous psilocybin administration and preparation*¹", was conducted by the Institute of Psychiatry, Psychology & Neuroscience (IoPPN) at King's College London in 2019. The results also showed there were no short or long term detrimental effects on thinking patterns or processing of emotions.

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 investigational drug was administered simultaneously to up to six participants, who all received 1:1 psychological support from trained therapists throughout the session, which lasted about six hours. The study involved a 12 week follow-up period. There were no serious adverse events and COMP360 psilocybin was found to be well-tolerated with no clinically-relevant negative effects on cognitive function.

Dr James Rucker, the study's lead author from King's IoPPN and honorary consultant psychiatrist at South London and Maudsley NHS Foundation Trust, said: "This rigorous study is an important first demonstration that the simultaneous administration of psilocybin is worth exploring further. If we think about how psilocybin therapy (if approved) may be delivered in the future, it's important to demonstrate the feasibility and the safety of giving it to more than one person at the same time, so we can think about how we scale the treatment up. This therapy has promise for people living with severe mental health problems, like treatment-resistant depression (TRD) and PTSD. They can be extremely disabling, distressing and disruptive, but current treatment options for these conditions are ineffective or partially effective for many people."

Dr Guy Goodwin, Chief Medical Officer, COMPASS Pathways, said: "This study was an early part of our clinical development programme for COMP360 psilocybin therapy. It explored the safety and feasibility of simultaneous psilocybin administration, with 1:1 support, in healthy participants, and provided a strong foundation to which we have now added positive results from our phase IIb trial in 233 patients with TRD, and from our open-label study of patients taking SSRI antidepressants alongside psilocybin therapy. We are looking forward to meeting with the FDA early in the year to finalise plans for our phase III programme, which we expect to begin in the third quarter 2022."

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¹The effects of psilocybin on cognitive and emotional functions in healthy participants: results from a phase 1, randomised, placebo-controlled trial involving simultaneous psilocybin administration and preparation ([DOI - 10.1177/02698811211064720](https://doi.org/10.1177/02698811211064720)) (James J Rucker, Lindsey Marwood, Riikka-Liisa J Ajantaival, Catherine Bird, Hans Eriksson, John Harrison, Molly Lennard-Jones, Sunil Mistry, Francesco Saldarini, Susan Stansfield, Sara J Tai, Sam Williams, Neil Weston, Ekaterina Malievskaia, and Allan H Young) was published in the *Journal of Psychopharmacology*.

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, COMPASS’s business strategy and goals, including its ability to launch and commercialise products, COMPASS’s expectations for the timing of its pivotal phase III programme and the potential for that or other trials to support regulatory filings and approvals, 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 and the effectiveness of its executive team. 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.

About King’s College London and the Institute of Psychiatry, Psychology & Neuroscience

[King’s College London](http://www.kcl.ac.uk) is one of the top 35 UK universities in the world **and one of the top 10 in Europe** (QS World University Rankings, 2020/21) 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 8,500 staff. King’s has an outstanding reputation for world-class teaching and cutting-edge research. The Institute of Psychiatry, Psychology & Neuroscience (IoPPN) at King’s 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.
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