



COMPASS Pathways to launch phase II trial of COMP360 psilocybin therapy for post-traumatic stress disorder

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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 will be conducting a phase II clinical trial to assess the safety and tolerability of COMP360 psilocybin therapy in post-traumatic stress disorder (PTSD). The study expands COMPASS's research pipeline in psilocybin therapy with COMP360, the company's proprietary formulation of synthetic psilocybin which COMPASS is currently developing for treatment-resistant depression.

The phase II, multicentre, fixed-dose open label COMP201 study will enrol 20 participants to evaluate the safety and tolerability of COMP360 psilocybin therapy in people who suffer with PTSD resulting from trauma experienced as adults. The study will begin at The Institute of Psychiatry, Psychology & Neuroscience (IoPPN) at King's College London. Participants will receive a single 25mg dose of COMP360 psilocybin, given in conjunction with specialist psychological support, in line with the COMP360 psilocybin therapy protocol, and will be followed up for 12 weeks. The primary endpoint of the study is to assess the safety of COMP360 psilocybin therapy. Secondary endpoints will measure efficacy in improving PTSD symptoms, functionality, and quality of life.

George Goldsmith, CEO and Co-founder, COMPASS Pathways, said, "We have made great progress in developing COMP360 psilocybin therapy for patients suffering with treatment-resistant depression, and are pleased to be able to expand development into the indication of PTSD, another area of significant unmet need. As many as one in 20 people in the UK suffer with PTSD and up to 40% of those are not helped by existing treatments. This is an urgent problem and we are determined to do what we can to transform mental health care and bring new, evidence-based therapies to those who so desperately need them."

Dr James Rucker, Consultant Psychiatrist and Senior Clinical Lecturer in Psychopharmacology at King's IoPPN, and Principal Investigator of the study, said, "The effects of PTSD can be extremely debilitating and current treatments aren't always effective. The clinical potential of psilocybin therapy is notable and thus a trial investigating it in PTSD is timely and necessary. We hope that, in time, our work will offer a new form of treatment for the severe and distressing symptoms that those with PTSD suffer so much from."

PTSD is a mental health condition that can impact quality of life and lead to diminished cognitive and psychosocial functioning, fractured relationships, inability to maintain employment, substance abuse, high healthcare utilisation costs, increased depression, and suicide risk. People who experience PTSD may relive their traumatic experience(s) through nightmares and flashbacks, have difficulty sleeping, and feel detached or estranged.ⁱ

The Adult Psychiatric Morbidity Survey estimated that one in 20 people in the UK suffer from PTSD, with similar rates for men and women.ⁱⁱ The symptoms of PTSD are often severe and long lasting and current treatment approaches are ineffective for many patients. First line treatment includes psychological interventions such as trauma-focused cognitive behavioural therapy followed by pharmacological approaches such as selective serotonin-reuptake inhibitors (SSRIs).^{iii,iv} Unfortunately, about 40% of those with PTSD will not improve with this treatment.^{v,vi} The PTSD Psychopharmacology Working Group recently described current treatment outcomes as "a crisis" and called for novel, effective and efficient trauma-focused interventions to be developed.^{vii}

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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 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.

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

[King's College London](https://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. www.kcl.ac.uk/ioppn @KingsIoPPN

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 or post-traumatic stress disorder, COMPASS's business strategy and goals, COMPASS's ability to continue to advance its research, including COMP360, COMPASS's expectations regarding the benefits of its psilocybin therapy, including COMP360 and COMPASS's ability to advance new psychedelic compounds in other areas of unmet mental health need. 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.

Enquiries

Media: Tracy Cheung, tracy@compasspathways.com, +44 7966 309024

Investors: Stephen Schultz, stephen.schultz@compasspathways.com, +1 401 290 7324

ⁱ US Department of Veteran Affairs (2021). PTSD: National Center for PTSD [Online]. Available at: https://www.ptsd.va.gov/understand/common/common_adults.asp [Accessed 01 November 2021]

ⁱⁱ McManus S, Bebbington P, Jenkins R, Brugha T. (eds.) (2016) Mental health and wellbeing in England: Adult Psychiatric Morbidity Survey 2014. Leeds: NHS Digital. p107

ⁱⁱⁱ National Institute for Health and Care Excellence (2018). Post-traumatic stress disorder, NICE guideline [NG116] [Online]. Available at: <https://www.nice.org.uk/guidance/ng116> [Accessed 01 November 2021]

^{iv} American Psychological Association (2017). Clinical Practice Guideline for the Treatment of Posttraumatic Stress Disorder (PTSD) in Adults [Online]. Available at: <https://www.apa.org/ptsd-guideline> [Accessed 01 November 2021]

^v Krediet E, Bostoen T, Breeksema J, et al. Reviewing the Potential of Psychedelics for the Treatment of PTSD, International Journal of Neuropsychopharmacology. 2020; 23(6) 385-400

^{vi} Berger W, Mendlowicz MV, Marques-Portella C, et al. Pharmacologic alternatives to antidepressants in posttraumatic stress disorder: a systematic review. Prog Neuropsychopharmacol Biol Psychiatry. 2009;33(2):169-180

^{vii} Krystal JH, Davis LL, Neylan TC, et al. It Is Time to Address the Crisis in the Pharmacotherapy of Posttraumatic Stress Disorder: A Consensus Statement of the PTSD Psychopharmacology Working Group [published correction appears in Biol Psychiatry. 2018 Feb 1;83(3):296]. Biol Psychiatry. 2017;82(7):e51-e59