

Compass Pathways initiates UK component of global phase 3 study of psilocybin treatment in treatment-resistant depression and launches new research center

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- UK sites to participate in part of pivotal phase 3 program following Medicines and Healthcare Regulatory Agency approval of study
- Research will take place in the UK, including at the newly opened Centre for Mental Health Research and Innovation in London, developed in partnership with South London and Maudsley NHS Foundation Trust and the Institute of Psychiatry, Psychology & Neuroscience at King's College London

LONDON, Nov. 15, 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 the initiation of the UK component of its phase 3 program of investigational COMP360 psilocybin treatment in treatment-resistant depression (TRD). The research will take place in multiple sites in the UK, including at the Centre for Mental Health Research and Innovation ("the Centre") in London, which officially opened today.

The ongoing phase 3 program is the largest randomized, controlled, double-blind psilocybin treatment clinical program ever conducted and follows promising results from Compass's phase 2b study of COMP360 psilocybin treatment. The phase 3 program consists of two pivotal trials (COMP 005 and COMP 006), and each trial has an integrated, long-term outcomes component.

COMP 006 will take place in the UK and globally and will study three dose arms of COMP360 (25mg, 10mg and 1mg). COMP 005 is a US-based trial examining the effect of a single 25mg dose of COMP360 psilocybin, compared with placebo.

Research at the new Centre for Mental Health Research and Innovation

The COMP 006 trial will be conducted at research sites across the UK, including at the new Centre for Mental Health Research and Innovation, which officially opened today.

The Centre was established to accelerate psychedelic research and develop new models of care for mental health in the UK, as part of a pioneering long-term strategic partnership between Compass, South London and Maudsley NHS Foundation Trust, and the Institute of Psychiatry, Psychology & Neuroscience (IoPPN) at King's College London.

Located at the Maudsley Hospital in South London, the dedicated and purpose-built space will be run by leading clinical investigators, Professor Allan Young, Head of Academic Psychiatry at King's College London, and Dr James Rucker, Consultant Psychiatrist and Lead of the Psychoactive Trials Group at King's College London. Research will initially focus on areas of urgent need, including TRD and anorexia nervosa.

The Centre will assist in the development of new models of care to help integrate these investigational treatments into health systems, if approved in the future. This will include evaluating real-world evidence, researching and developing digital technologies that may help to deliver personalized, predictive and preventative care models, and conducting therapist training.

Commentary

"Every 40 seconds, someone dies from suicide; tens of millions more live with mental health conditions for which there is no good standard of care," said Kabir Nath, CEO, Compass Pathways. "The launch of our phase 3 clinical study in treatment-resistant depression here in the UK is an important step in developing innovations that are urgently needed, and we recognize the important role that public-private partnerships play in this."

Kabir continued, "We're proud to partner with South London and Maudsley NHS Foundation Trust and King's College London to open the new Centre for Mental Health Research and Innovation. Together, we are conducting cutting-edge research to develop new solutions for mental illnesses and ensure these potential treatments are broadly and equitably accessible to those who need them the most."

David Bradley, Chief Executive of South London and Maudsley NHS Foundation Trust, said, "We are excited to be running part of this pivotal phase 3 study at the new Centre for Mental Health Research at our Maudsley Hospital site in South London."

He continued, "The newly launched Centre is part of a research partnership which will help to develop innovative treatment with the goal of improving mental health care for people across the UK. Our world-leading clinicians will work closely with researchers at the new Centre and will begin with a focus on areas of urgent need, such as

anorexia nervosa and treatment-resistant depression.”

Professor Allan Young, Head of Academic Psychiatry, at King’s College London said: “Today marks a milestone for research into the use of psychedelics to treat mental health conditions. Over several years we have moved to phase 3 clinical trials for psilocybin and treatment-resistant depression, an achievement that would not have been possible without the facilities and staff of the NIHR King’s Clinical Research Facility. Now with this new Centre, the continuing partnership between Compass Pathways, King’s College London and South London and Maudsley is embarking on the next stage of research where we can evaluate the safety and effectiveness of psychedelics to treat a range of mental health conditions, explore the mechanisms behind how psychedelics might work and assess the feasibility for their delivery at scale.”

About Compass Pathways

Compass Pathways plc (Nasdaq: CMPS) is 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 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 COMP 360 psilocybin therapy in TRD, the largest randomized, controlled, double-blind psilocybin therapy 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 high dose of COMP360 psilocybin with psychological support. We are also conducting phase 2 clinical studies of COMP360 psilocybin therapy for post-traumatic stress disorder (PTSD) and anorexia nervosa. Compass Pathways 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.

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”, “will”, “could”, “would”, “expect”, “intend”, “plan”, “anticipate”, “believe”, “potential” and “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 investigational COMP360 psilocybin therapy as a treatment for depression, post-traumatic stress disorder or anorexia nervosa, the potential for the pivotal phase 3 program or other trials to support regulatory filings and approvals, Compass’s business strategy and goals, Compass’s expectations and plans regarding the Centre for Mental Health Research and Innovation, Compass’s ability to continue to advance its research or develop plans to bring COMP360 psilocybin therapy to patients, including COMP360, and Compass’s expectations regarding the benefits of its investigational 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: clinical development is lengthy and outcomes are uncertain, and therefore our clinical trials may be delayed or terminated; 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 development efforts and our business strategy to set up research facilities and innovation labs, such as the Centre for Mental Health Research and Innovation involves significant costs and resources and may be unsuccessful; and our efforts to obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment, 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.

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

King's College London is amongst the top 35 universities in the world and top 10 in Europe (THE World University Rankings 2023), and one of England's oldest and most prestigious universities.

With an outstanding reputation for world-class teaching and cutting-edge research, King's maintained its sixth position for 'research power' in the UK (2021 Research Excellence Framework).

King's has more than 33,000 students (including more than 12,800 postgraduates) from some 150 countries worldwide, and some 8,500 staff. The Institute of Psychiatry, Psychology & Neuroscience (IoPPN) at King's is a leading centre for mental health and neuroscience research in Europe. It produces more highly cited outputs (top 1% citations) on psychiatry and mental health than any other centre (SciVal 2021), and on this metric has risen from 16th (2014) to 4th (2021) in the world for highly cited neuroscience outputs. In the 2021 Research Excellence Framework (REF), 90% of research at the IoPPN was deemed 'world-leading' or 'internationally excellent' (3* and 4*). World-leading research from the IoPPN has made, and continues to make, an impact on how we understand, prevent and treat mental illness, neurological conditions, and other conditions that affect the brain.

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About South London and Maudsley NHS Foundation Trust

South London and Maudsley NHS Foundation Trust is a large and complex multi-site provider of mental health services – providing the widest range of NHS mental health services in the UK. We aim to make a difference to people's lives by seeking excellence in all areas of mental health and wellbeing.

Our 6,000 staff serve a local population of 1.3 million people and we offer more than 260 services including inpatient wards, outpatient and community services across Lambeth, Lewisham, Southwark and Croydon. We also provide substance misuse services for people who are addicted to drugs and alcohol.

As well as serving the communities of south London, we provide more than 20 specialist services for children and adults across the UK including perinatal services, eating disorders, psychosis and autism. Find out more about our five-year strategy Aiming High; Changing Lives <https://slam.nhs.uk/strategy>

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A video accompanying this announcement is available

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