



American Medical Association to Issue First New Code for Psychedelic Therapies

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COMPASS Pathways and MAPS PBC submitted joint application for new code to facilitate access to psychedelic therapy in the US, if approved

LONDON and SAN JOSE, Calif., May 02, 2023 (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, and MAPS Public Benefit Corporation (MAPS PBC), a clinical-stage company dedicated to changing the way mental health conditions are treated, today announced that the American Medical Association (AMA) has approved a Current Procedural Terminology (CPT[®]) III code for psychedelic therapies. The full details of the code are expected to be released by the AMA in July 2023 and the code will go into effect when it is published on January 1, 2024. Once effective, the CPT code will provide physicians and other qualified healthcare professionals a means to code and seek reimbursement for delivering psychedelic therapies.

The application for the new CPT III code was the result of a collaboration between MAPS PBC and COMPASS Pathways to facilitate reimbursement and ultimately access to psychedelic therapies in the US, if approved by the US Food Drug Administration (FDA). Both companies are working to develop and, subject to FDA approval, commercialize psychedelics as part of a new treatment paradigm for individuals with mental health conditions. COMPASS Pathways is conducting a [phase 3 program](#) of investigational COMP360 psilocybin therapy in treatment-resistant depression (TRD), having already published [positive results](#) in the *New England Journal of Medicine* from its phase 2b study of COMP360 in TRD, in the largest study of its kind. MAPS PBC has completed [two phase 3 clinical trials](#) evaluating MDMA-assisted therapy as a potential treatment for post-traumatic stress disorder (PTSD), both of which met their pre-specified primary and secondary endpoints. This new code may provide a mechanism by which these new treatments being developed by COMPASS and MAPS PBC could be reimbursed if they are approved by the FDA.

"This is a major step forward to enabling broad and equitable access to psychedelic therapies," said Kabir Nath, CEO, COMPASS Pathways. "This collaboration with MAPS PBC to develop a new CPT code aims to ensure that psychedelic therapies, if approved, could be integrated into healthcare systems, reimbursed by payers, and made available to the people who need them."

On March 3, 2023 the AMA [published](#) the Summary of Panel Actions which included the acceptance of the new CPT III code. The application was titled, "Continuous In-Person Monitoring and Intervention during Psychedelic Medication Therapy." CPT III codes are a set of temporary codes assigned to emerging technologies, services and procedures. They are intended to be used for data collection to substantiate more widespread usage or to provide documentation for the FDA approval process.

"Psychedelic-assisted therapies represent a potential new frontier in the treatment of mental health conditions and our top priority is ensuring there is a path forward to integrate them into the healthcare system, if FDA approved," said Amy Emerson, CEO, MAPS PBC. "Strong collaborations like this one demonstrate that by working together, we can move closer to our collective goal of helping people currently underserved by existing treatments for mental health conditions."

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 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 randomised, 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 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”, “anticipate”, “believe”, “contemplate”, “seek”, “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 Company’s plans and expected timing for its phase 3 program in TRD and the potential for that or other trials to support regulatory filings and approvals, the safety or efficacy of its investigational COMP360 psilocybin therapy, including for treatment of TRD, anorexia nervosa, and PTSD, and COMPASS’s expectations regarding the potential impact of the CPT III codes on reimbursement for and access to COMP360 psilocybin therapy, if FDA approval is obtained. 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, or may never advance; 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; the American Medical Association may change the scope of the CPT III code prior to publication in July 2023, which may negatively impact our expectations regarding reimbursement for COMP360 psilocybin therapy, if approved, and 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.

ABOUT MAPS PUBLIC BENEFIT CORPORATION (MAPS PBC)

MAPS Public Benefit Corporation (MAPS PBC) is focused on developing and commercializing prescription psychedelics to bring better treatments to those living with mental health conditions. Founded in 2014, MAPS PBC is a subsidiary of the Multidisciplinary Association for Psychedelic Studies, a 501(c)(3) non-profit organization. For more information, please visit www.mapsbcorp.com.

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