American Medical Association Releases Language of First New Current Procedural Terminology Code for Psychedelic Therapies

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- New code will facilitate reimbursement for psychedelic therapy in the US, if approved
- COMPASS Pathways to hold webinar on new code on Tuesday, July 11, 8:00 am EDT (1:00 pm BST)

LONDON, July 06, 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 that the American Medical Association has released the language of its new Current Procedural Terminology (CPT®) III code for *Continuous In-Person Monitoring and Intervention During Psychedelic Medication Therapy*. The code will go into effect and will be published in the CPT manual on January 1, 2024.

The approval of the new category CPT III code, announced in May following an application by COMPASS and MAPS Public Benefit Corporation (MAPS PBC), was supported by the American Psychiatric Association, American Psychological Association and the National Association of Social Workers. Once effective, the new code will provide a mechanism to track and report the delivery of psychedelic treatments and will cover, subject to FDA approval, COMPASS's COMP360 psilocybin treatment, which is currently in late-stage development for treatment-resistant depression, and MAPS' MDMA-AT for post-traumatic stress disorder.

The new code, reported in increments of one hour, will cover multiple psychedelic compounds with psychological support models, if approved, as well as variable staffing structures and numbers and credentials of qualified healthcare professionals (QHPs). It will also offer a sub-code for the involvement of non-QHP clinical staff. The use of this category III tracking code will be key to developing optimal permanent and valued category I codes for psychedelic therapies as close as possible to their potential FDA approval.

Kabir Nath, Chief Executive Officer of COMPASS Pathways, said, "This new CPT III code will help ensure broad and equitable access to psychedelic therapies, if approved, for people who urgently need new options to treat their mental health conditions. The language released by the American Medical Association shows that the CPT code will facilitate accurate tracking of the work required to support effective, regulated and reimbursed delivery of these new potential treatments."

Webinar
COMPASS will hold a webinar on the new code for investors, analysts and media on Tuesday, July 11, 2023, at 8:00 am EDT (1:00 pm BST). The webinar will feature:

- Dr. Geoffrey Grammer, Chief Medical Officer at Greenbrook NeuroHealth Centers
- Dr. Marketa Wills, Chief Medical Officer at Johns Hopkins HealthCare
- Kabir Nath, Chief Executive Officer at COMPASS
- Dr. Steve Levine, Senior Vice President of Patient Access and Medical Affairs at COMPASS.

The one-hour moderated discussion will focus on the impact of the new code for healthcare delivery professionals and payers, and the role of the code in establishing commercial models for psychedelic treatment if these therapies receive regulatory approval.

Please register in advance here to access the webinar and obtain a local or toll-free phone number and personal pin. A live audio webcast of the webinar will be accessible from the "Events" page of the Investors section of the COMPASS website. The replay of the webcast will be accessible for 30 days following the event. For more information, please visit ir.compasspathways.com.

About COMPASS Pathways

COMPASS Pathways plc (Nasdaq: CMPS) is a biotechnology 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 treatment, 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 COMP360 psilocybin treatment in TRD, the largest randomized, controlled, double-blind psilocybin treatment 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 25mg dose of COMP360 psilocybin with psychological support. We are also conducting phase 2 clinical studies of COMP360 psilocybin treatment 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”, “believe”, “estimate”, “predict”, “possible”, “potential” 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 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 treatment, including for treatment of TRD, anorexia nervosa, and PTSD,, the potential impact of the temporary CPT III codes on reimbursement for and access to COMP360 psilocybin treatment, if FDA approval is obtained, and COMPASS’s expectations regarding the potential issuance of permanent CPT I codes for psychedelic treatments. 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; the possibility of unfavorable results from additional clinical trials of COMP360 psilocybin treatment or from subsequent analysis of existing data or new data received from additional ongoing and future studies of COMP360 psilocybin treatment; 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 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.

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