Open-label study of COMP360 psilocybin therapy for depression in cancer patients demonstrates feasibility of simultaneous psilocybin administration in small groups

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Investigator-initiated study shows remission in major depression symptoms for 50% of participants

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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, welcomed the topline data shared today from an open-label study of psilocybin therapy for depression in cancer patients. Within one week of a single administration of COMP360 psilocybin therapy, 50% of participants achieved remission in depression symptoms, which was sustained for the eight week follow-up period.

This investigator-initiated feasibility study was conducted by Maryland Oncology Hematology at the Aquilino Cancer Center in Rockville, Maryland, USA. It was an open-label study involving 30 patients with cancer diagnosis and major depressive disorder (MDD), all of whom completed the study. Half of the participants had previously been treated for their current episode of depression with antidepressants and all were receiving active treatment for cancer; 19 participants had no previous experience with psychedelic substances. Patients were given a 25mg dose of COMP360 psilocybin in conjunction with psychological support from specially trained therapists, following the COMP360 psilocybin therapy protocol. Unlike earlier psilocybin therapy trials for depression in cancer, this study was not restricted to patients with late-stage cancer. The Maryland team also pioneered simultaneous group administration in a cancer care centre, with two to four patients being given psilocybin at the same time, with 1:1 therapist support. This tested the value of group support for cancer patients as well as the potential for increased scalability in providing psilocybin therapy in real world settings.

COMP360 psilocybin therapy was found to be generally well tolerated with no treatment-related serious adverse events. Adverse effects seen on the day of dosing were as expected from experience in healthy volunteer groups and included headache, changes in sensory perception and mood alteration.

Patients were assessed using the Montgomery-Åsberg Depression Rating Scale (MADRS), a clinician-administered symptom questionnaire. A sustained response rate (a decrease of ≥50% in the MADRS score from baseline observed at any visit up to and including week 3, and also fulfilled at week 8) was seen by 24 patients; 15 patients showed remission of depression symptoms (a MADRS score <10) one week after a single dose of psilocybin, which was sustained up to eight weeks. The 30 patients in the study began with an average MADRS score of 25.9, representing moderate depression. After psilocybin therapy, the average score dropped by 19.1 points. The study investigators noted that this was an open-label study in which neither patients nor raters were blinded, so there is a significant risk that the results incorporate a large expectancy bias.

Dr Manish Agrawal, medical oncologist, Co-director of Clinical Research at the Aquilino Cancer Center, and the trial's Principal Investigator, said: "A cancer diagnosis can change the course of a patient's life. For complete cancer care, we need to focus on whole-person healing and include the mental wellbeing of our patients. This is not widely addressed today, but it's time to do something about it. These study results have shown that psilocybin therapy may be helpful with MDD in cancer, and we look forward to doing further analysis and following up with additional studies. While it's premature to draw any definitive conclusions from this study, simultaneous administration appears to be well tolerated and feasible, and the results are promising and worthy of further research."

Professor Guy Goodwin, Chief Medical Officer, COMPASS Pathways, said: "These preliminary findings suggest COMP360 psilocybin therapy was well tolerated by cancer patients with major depressive disorder. It is promising to see that this may be a feasible fast-acting therapy for depressed patients with a significant physical co-morbidity. This would certainly be welcome in conditions where depression is difficult to treat in a timely way."

Professor Goodwin added: "This open-label MDD study is very different from the randomised, controlled, double-blinded phase IIb study that COMPASS has conducted for patients with treatment-resistant depression. Nevertheless, it has given a positive signal of the potential for COMP360 psilocybin therapy, and we are delighted to see that a number of patients showed signs of improvement. We are now considering how we take this forward with future studies as we continue to develop a broad portfolio of therapies in areas of significant unmet need in mental health care."

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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, 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

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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, COMPASS's business strategy and goals, the benefits of additional patent protection to help achieve these goals, COMPASS’s expectations regarding the benefits of its psilocybin therapy; and the potential for topline, preliminary open label data from an investigator-initiated study using COMP360 psylocibin therapy to be predictive of results in other trials involving COMP360. 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