

New England Journal of Medicine publishes exploratory study showing signals of positive activity in COMP360 psilocybin compared with escitalopram for major depressive disorder

2021-04-15

Study concludes that psilocybin findings should be explored further in larger studies

London, UK, April 15, 2021 (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, welcomed a study published in the **New England Journal of Medicine** (NEJM) yesterday, which showed signals of positive activity in COMP360 psilocybin compared with the standard antidepressant escitalopram, for major depressive disorder (MDD).

The study was designed and conducted by a research team at Imperial College London, using COMPASS's COMP360 psilocybin.

This was an exploratory, randomised, double-blind clinical study. Its aim was to compare the efficacy and mechanisms of action of psilocybin with a six-week course of escitalopram, a selective serotonin reuptake inhibitor (SSRI), for MDD.

The study included 59 participants; 30 were randomly assigned to the psilocybin arm, and 29 to the escitalopram arm. Participants in the psilocybin arm received two doses of 25mg psilocybin three weeks apart, with psychological support delivered prior to, during and after each psilocybin administration, plus six weeks of daily placebo capsules. The escitalopram arm received two doses of 1mg psilocybin (presumed negligible effect) three weeks apart, with equivalent psychological support to the psilocybin arm, plus six weeks of daily escitalopram capsules, 10mg for the first three weeks titrated to 20mg for the following three weeks.

The study authors, from Imperial College London, noted that the study was not powered to detect a difference between psilocybin and escitalopram. As reported in the NEJM, the primary efficacy measure, the change from baseline in the self-rated 16-item Quick Inventory of Depressive Symptomatology (QIDS-SR-16) total score at six weeks, did not show a significant difference between the two groups, with a two point difference favouring the psilocybin group compared with the escitalopram group. This trend favouring psilocybin was present from week one.

Secondary outcomes including clinician-rated depression scales, response and remission, signalled the antidepressant effects of both agents; psilocybin showed numerical advantages on clinical measures compared with escitalopram. On the clinician-rated depression scales, the change from baseline at week six on the Montgomery-Asberg Depression Rating Scale (MADRS), showed a 7.2 point treatment difference favouring psilocybin, while the Hamilton Depression Rating Scale (HAM-D-17) showed a 5.3 point treatment difference favouring psilocybin. Response rates (a 50% or greater reduction on the QIDS-SR-16 total score from baseline) at week six were 70.2% for the psilocybin arm compared with 48.0% for the escitalopram arm, and remission rates (defined as a QIDS-SR-16 total score ≤ 5) at week six were 57.1% and 29.1%, respectively. Similar patterns favouring psilocybin were found in other secondary endpoints measuring work and social functioning, anxiety, avoidance, anhedonia, and wellbeing. Such secondary endpoints were uncorrected for multiplicity.

Adverse event rates and severity were largely comparable across conditions. Adverse events in the psilocybin arm were typically transient, occurring and resolving within 24 hours of dosing days, with the most commonly reported adverse event being transient headaches. No Serious Adverse Events were reported.

“In a field of research where it is very difficult to separate treatments in head-to-head comparative efficacy trials, this study found signals favouring psilocybin therapy over escitalopram. This is an encouraging investigator-initiated study that supports the need for additional clinical investigations in larger, well-powered studies to more accurately determine the efficacy of COMP360 psilocybin in MDD”, said George Goldsmith, CEO and Co-founder of COMPASS Pathways. “At COMPASS, we are already committed to a full clinical development programme of psilocybin therapy in treatment-resistant depression, and we know there is much more work to be done so that we can bring evidence-based innovation to patients who have run out of options in a number of mental health illnesses.”

-Ends-

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 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”, “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 efficacy of COMP360 psilocybin therapy as a treatment for depression, COMPASS’s business strategy and goals, COMPASS’s ability to continue to advance its research, including COMP360, and COMPASS’s expectations regarding the benefits of its psilocybin therapy, including 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 7423