



NEWS RELEASE

COMPASS Pathways announces publication of first study evaluating potential of AI model to predict outcomes of COMP360 psilocybin treatment in treatment-resistant depression

2023-09-06

LONDON, Sept. 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 the publication of a new paper in *Psychopharmacology*, which showed the results of a retrospective study that evaluates the potential of its AI technologies to support investigational COMP360 psilocybin treatment in treatment-resistant depression (TRD). The paper was published on August 22, 2023.

The peer-reviewed paper shows the AI model has the potential to predict outcomes of the investigational COMP360 psilocybin treatment in people with TRD up to 12 weeks after treatment using recordings taken during the integration session 24 hours post administration. Further research and studies are required to validate this model and to evaluate its capabilities to predict responder status pre-treatment.

Using a large language model, COMPASS created a machine learning algorithm that assessed the emotional sentiment of 101 English speaking participants from the company's recent randomized double-blind phase 2b study in TRD. The sentiment scores, as measured by valence (happiness to sadness) and arousal (intensity of emotion), were then used in the second stage of the machine algorithm to predict patient response as measured by the Montgomery-Asberg Depression Rating Scale (MADRS) at three weeks and three months post-drug administration. This model yielded a cross-validated accuracy of 85% and 88% at the three and twelve-week timepoints, respectively. The Area Under the Curve (AUC) results were comparable with values of 88% and 85% at the three and twelve-week timepoints.

“These results are exciting because they signal that we could potentially use AI technology to predict long-term patient response in the emerging field of psilocybin treatment,” said Kabir Nath, CEO of COMPASS Pathways. “We believe this could also support the delivery of more personalized care in the long-term for people suffering from TRD.”

“Our goal is to use technology to move clinical psychology toward precision medicine,” said Greg Ryslik, Chief Technology Officer at COMPASS. “By using Natural Language Processing (NLP) to identify key linguistic and speech-based digital biomarkers, we have the opportunity to further understand the presentation of TRD and help provide a deeper understanding of treatment-resistant depression as a whole if unique patterns between individuals emerge.”

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, COMPASS’s expectations regarding the potential benefits of its AI model and its ability to develop technologies that may predict treatment outcomes, the safety or efficacy of its investigational COMP360 psilocybin treatment, including for treatment of TRD, anorexia nervosa, and PTSD, COMPASS’s expectations regarding its ongoing preclinical work and clinical trials and development efforts, the potential for COMPASS’s pivotal phase 3 program or other trials to support regulatory filings and approvals and COMPASS’s expectations regarding the benefits of its COMP360 psilocybin treatment. 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: the outcomes of future studies of this AI model are uncertain and may never establish the accuracy or reliability of such technology; 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.

Enquiries

Media: Amy Lawrence, media@compasspathways.com, +44 7813 777 919

Investors: Stephen Schultz, stephen.schultz@compasspathways.com, +1 401 290 7324