Opinion paper calls for clarity on the definition of “psychedelic-assisted therapy” using psilocybin

July 13, 2023

- Leading psychiatrists and researchers examine common assumptions about the term “psychedelic-assisted psychotherapy” and the role of psychotherapy when evaluating psilocybin treatment.
- Authors highlight the need for clarity in terminology and definition to accurately assess the efficacy and safety of psilocybin treatment.

LONDON, July 13, 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 paper in the *American Journal of Psychiatry* that examines the definition of "psychedelic-assisted psychotherapy" using psilocybin and offers a new way of thinking about and describing this potential new treatment in psychiatry. The article is authored by leading psychiatrists and researchers, including COMPASS's Chief Medical Officer, Dr. Guy Goodwin, and Co-founder and COMPASS board member, Dr. Ekaterina Malievskaia.

Psychedelic drugs, such as psilocybin, can produce a powerful experience for patients, and are being studied to understand their potential in several mental health conditions, including treatment-resistant depression. This potential new treatment is often referred to as “psychedelic-assisted psychotherapy” or “psychedelic-assisted therapy.” The authors of the paper examine the definitions as they relate to psilocybin treatment and offer these primary conclusions:

- **Psychological support is an essential element of psilocybin treatment but is not an independent psychotherapy as commonly understood**. Psychological support is provided to patients to help them prepare for their experience and to safeguard them throughout the treatment. The intense psychedelic states associated with psilocybin are largely incompatible with simultaneous evidence-based psychotherapy. A therapist is present during the administration of psilocybin treatment to provide non-directive support, not to interpret the experience. This has been the case in virtually all the formal historical clinical trials of psilocybin.
- **More research is needed to understand how to optimize psilocybin treatment.** The first steps have been taken to create a safe and effective framework for psilocybin treatment to advance through the regulatory process. If psilocybin treatment is approved by regulatory authorities, this baseline standard of care could be built upon by researchers interested in exploring further therapeutic developments.
- **Clarity on terminology is needed to better define psilocybin treatment.** For patients to access a new treatment, it must first be approved by regulatory bodies such as the US Food and Drug Administration and the European Medicines Agency. Regulators evaluate and approve investigational medicinal products based on safety, quality and efficacy. They have not historically evaluated or regulated psychotherapy. To achieve regulatory approval, the drug effect needs to be established unambiguously in clinical trials, which is only possible if any psychological support is not an alternative treatment in itself and is applied in a consistent way. As such, there is a need for clarity on how this type of treatment is characterized. In this case of psilocybin administration with psychological support, the authors suggest using the term “psilocybin treatment.”

Dr. Goodwin said, “The evidence we have seen from the most rigorous studies of psilocybin treatment to date, suggests that the efficacy of the treatment comes primarily from the drug itself, while psychological support is essential for safeguarding patients. This clarity is important in the assessment of efficacy and safety of psilocybin, alongside standardized psychological support. Our ongoing phase 3 program of COMP360 psilocybin treatment for treatment-resistant depression aims to generate additional evidence in the context of this efficacy and safety assessment.”

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 US 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 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 “aim”, “may”, “will”, “could”, “should”, “expect”, “intend”, “believe”, “predict”, “possible”, “potential”, “suggest”, “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 safety or efficacy of its investigational COMP360 psilocybin treatment, including for treatment of TRD and other mental health conditions, 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: 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 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