

# COMPASS Pathways completes COMP360 psilocybin therapy administration for 216 patients in large-scale phase IIb psilocybin therapy trial for treatment-resistant depression

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# COMPASS on track to report data in late 2021

London, UK, June 28, 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, announced today that it has completed psilocybin administration to the target 216 patients in its phase IIb clinical trial of COMP360 psilocybin therapy for treatment-resistant depression. This is the world's largest psilocybin therapy trial to date.

The trial is a randomised controlled, double-blinded, dose-ranging study, investigating the safety and efficacy of psilocybin therapy and comparing a 25mg and 10mg dose of COMP360 psilocybin with a 1mg dose, administered in conjunction with psychological support from specially trained therapists. The 216<sup>th</sup> patient in the trial had their psilocybin session late last week. Although the target of 216 patients has been achieved and enrolment has now been closed, all enrolled patients who are in the run-in period and have not yet had their psilocybin therapy session, will remain in the trial. This means the number of patients included in the final analysis will be approximately 230, with all psilocybin sessions expected to be completed by 8 July.

Patients are followed-up for 12 weeks after their psilocybin session. COMPASS remains on track to report data in late 2021.

Sue Stansfield PhD, Senior Vice-President, Clinical Operations, COMPASS Pathways, said, "Thank you to everyone on the team and to all our partners and trial sites who have kept this trial going over the last year, despite the pandemic. The safety of patients and of our teams has always been our first priority, and we have introduced measures such as air filtration units and therapists wearing clear masks, to ensure patients were as comfortable as possible in the midst of all the COVID precautions."

George Goldsmith, CEO and Co-founder, COMPASS Pathways, said, "Completing recruitment to our trial is a tremendous milestone and a huge step forward towards our goal of getting psilocybin therapy to patients in need. We are fortunate to be doing this in collaboration with hundreds of talented and dedicated people from our 22 trial sites in 10 countries - including investigators, raters, study coordinators and nurses, therapists, and pharmacists – as well as our supply chain and clinical research partners. This has been an amazing effort by the whole team, who are delivering the world's largest psilocybin therapy clinical trial, in the middle of a pandemic, and with all the uncertainties and changes brought on by national lockdowns and site closures.

"We'd like to recognise and thank everyone who helped to make this trial happen, including all the patients who participated. We are now looking forward to completing the trial, and analysing and sharing the data later in the year. COMPASS is well financed following our recent fundraising of over \$165m. We expect to be ready to commence phase III trials as soon as we receive regulatory support to do so, based on our phase IIb results."

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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 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, the expected timing for reporting data related to COMP360, 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