A significant milestone in mental health research

Results of a phase 2b clinical trial of COMP360 psilocybin therapy for treatment-resistant depression

For any questions, or to arrange an interview, please contact **media@compasspathways.com** or call Amy Lawrence **+44 7813 777 919**

Please visit **www.compasspathways.com** for more information.

COMP360

COMPASS's investigational, proprietary formulation of synthetic psilocybin is administered in conjunction with psychological support from specially trained therapists

COMP360 has been designated a Breakthrough Therapy by the US FDA and has received Innovative Licensing and Access Pathway designation in the UK for treatment-resistant depression

Treatment-resistant depression (TRD): significant unmet medical need

100 million people suffer with depression which is not helped by existing treatments[1]

Associated with longer depressive episodes, higher risk of suicide, lower productivity at work, greater economic burden[2-4]

Clinical development programme

Phase 1

Completed **2019**

89 healthy participants

Phase 2b

Dose-finding study

COMP360 psilocybin therapy administration completed **July 2021**

World's largest psilocybin therapy study

Topline data presented at American Psychiatric Association Annual Meeting in **May 2022**

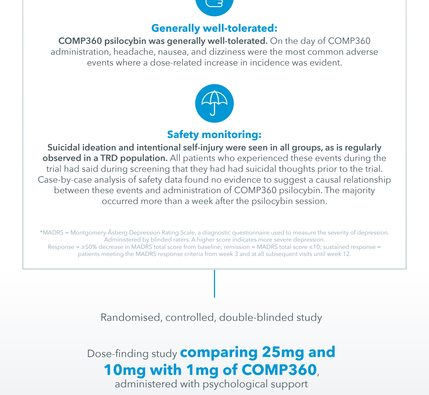
Published in The New England Journal of Medicine[5] **November 2022**

Phase 3

Design of the two pivotal trials in phase 3 clinical programme announced in **October 2022**

Large-scale pivotal trials, prior to application for marketing approval

22 sites
10 countries



233 TRD patients
(exceeding target recruitment of 216)

Key results:

Rapid reduction in symptoms after single dose:
Approximately 30% of patients in the 25mg group were in remission at week three (29.1%).

Patients who received a single 25mg dose of COMP360 psilocybin, in combination with psychological support, experienced a highly statistically significant, rapid reduction in symptoms of depression at three weeks: the difference between the 25mg group and 1mg group was -6.6 on the MADRS* depression scale at Week 3, p<0.001. These treatment group differences were observed from the day after administration.

Sustained response:
Double the number of patients who received a 25mg dose had a sustained response at week 12, compared to those who received 1mg (20.3% of patients in the 25mg group vs 10.1% in the 1mg group).

Generally well-tolerated:
COMP360 psilocybin was generally well-tolerated. On the day of COMP360 administration, headache, nausea, and dizziness were the most common adverse events where a dose-related increase in incidence was evident.

Safety monitoring:
Suicidal ideation and intentional self-injury were seen in all groups, as is regularly observed in a TRD population. All patients who experienced these events during the trial had said during screening that they had had suicidal thoughts prior to the trial. Case-by-case analysis of safety data found no evidence to suggest a causal relationship between these events and administration of COMP360 psilocybin. The majority occurred more than a week after the psilocybin session.

*MADRS = Montgomery Åsberg Depression Rating Scale, a diagnostic questionnaire used to measure the severity of depression. Administered by blinded raters. A higher score indicates more severe depression.
Response = ≥50% decrease in MADRS total score from baseline; remission = MADRS total score ≤10; sustained response = patients meeting the MADRS response criteria from week 3 and at all subsequent visits until week 12.

Randomised, controlled, double-blinded study

Dose-finding study **comparing 25mg and 10mg with 1mg of COMP360**, administered with psychological support

Patients followed up for **12 weeks**

Our goal is to make COMP360 psilocybin therapy accessible to patients with serious mental health illnesses

Large-scale **phase 2b trial** - data generated

Pivotal phase 3 trials

Regulatory approval

Reimbursement and integration into health systems

Widespread access for patients with TRD

Additional indications for COMP360 psilocybin therapy, as well as new compounds developed

"We saw positive results in a particularly difficult to treat group of patients. We look forward to starting our phase 3 programme later this year, moving us closer to providing COMP360 psilocybin with psychological support for patients who desperately need it."

Dr Guy Goodwin, Chief Medical Officer, COMPASS Pathways

COMPASS Navigating Mental Health Pathways

1. World Health Organization. Depression and other common mental disorders: global health estimates. 2017. https://apps.who.int/iris/handle/10665/254610. License: CC BY-NC-SA 3.0 IGO
2. Johnston KM, Powell LC, Anderson IM, Szabo S, Cline S. The burden of treatment-resistant depression: A systematic review of the economic and quality of life literature. Journal of Affective Disorders. 2019;242:195-210.
3. Mrazek DA, Hornberger JC, Altar CA, Degtiar I. A Review of the Clinical, Economic, and Societal Burden of Treatment-Resistant Depression: 1996-2013. Psychiatric Services. 2014;65(8):977-987.
4. Jaffe DH, Rive B, Denee TR. The humanistic and economic burden of treatment-resistant depression in Europe: A cross-sectional study. BMC psychiatry. 2019;19(247).
5. Goodwin G, Aaronson S, Alvarez O, et al. Single-Dose Psilocybin for a Treatment-Resistant Episode of Major Depression. New England Journal of Medicine. 2022; 387:1637-1648. https://doi.org/10.1056/nejmoa2206443.

Created November 2022