

A significant milestone in mental health research

Completing a phase IIb clinical trial in psilocybin therapy for treatment-resistant depression



Psilocybin therapy: one of the most promising innovations in psychiatry today

COMP360

COMPASS's synthetic psilocybin is administered in conjunction with psychological support from specially trained therapists

COMP360 has been designated a Breakthrough Therapy by the US FDA

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

100 million people

suffer with depression which is not helped by existing treatments

Associated with longer depressive episodes, higher risk of suicide, lower productivity at work, greater financial burden

Clinical development programme

Phase I

Completed **2019**

89 healthy participants

Phase IIb

Dose-finding study

COMP360 psilocybin therapy administration completed **July 2021**

World's largest psilocybin therapy study

Topline data announced in **November 2021**

Phase III

To follow in **2022**

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

22 sites
10 countries



233 TRD patients
(exceeding target recruitment of 216)

>300 people involved in the trial including:



Principal and sub-investigators



Study co-ordinators



Study nurses



Therapists



Pharmacists



Raters



Clinical research organisation partners and suppliers

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**

Making psilocybin therapy accessible to patients with serious mental health illnesses



"This has been an amazing effort by the whole team and is a huge step forward towards our goal of getting psilocybin therapy to patients in need"

George Goldsmith, CEO and Co-founder, COMPASS Pathways