Completing a phase IIb clinical trial in COMP360 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.

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

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
July 2021

Phase III
To follow in
2022
Larger-scale pivotal trials, prior to application for marketing approval

22 sites
10 countries

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

Phase IIb trial – data generated
Pivotal phase III trials – data generated
Regulatory approval
Widespread access for patients
Additional indications for COMP360 psilocybin therapy, as well as new compounds developed

A significant milestone in mental health research

“Making COMP360 psilocybin therapy accessible to patients with serious mental health illnesses

>300 people involved in the trial

Pharmacies

Randomised, controlled, double-blinded study

Study nurses

Therapists

Clinical research organisation, patients and suppliers

Principal and sub-investigators

Study co-ordinators

Patients followed up for 12 weeks

“Making COMP360 psilocybin therapy accessible to patients with serious mental health illnesses

George Goldsmith, CEO and Co-founder, COMPASS Pathways

"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"