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 from depression which is not helped by existing treatments.

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

Clinical development programme

Phase I
- Completed in 2019
- 89 healthy participants

Phase IIb
- Randomised, controlled, double-blinded study
- Dose-finding study comparing 25mg and 10mg with 1mg of COMP360, administered with psychological support
- 233 TRD patients (exceeding target recruitment of 216)
- To follow in 2022
- Larger scale pivotal trials, prior to application for marketing approval

Phase III
- Topline data announced in November 2021

>300 people involved in the trial industry

Dose-finding study
- COMP360 administration completed in July 2021
- World’s largest psilocybin therapy study
- Phase III trial and pivotal trials
- Regulatory approval
- Reimbursement
- Widespread access for patients with TRD
- Additional indications for psilocybin therapy, as well as new compounds developed

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