The safety and efficacy of COMP360 psilocybin therapy in treatment-resistant depression: Results from a phase IIb randomized controlled trial

Guy M. Goodwin1, Susan C. Stansfield2, David J. Hellerstein3, Allan H. Young4, Ekaeterina Mallevskia5

1COMPASS Pathfinder Ltd, London, United Kingdom (UK). 2Columbia University Department of Psychiatry and the New York State Psychiatric Institute, New York, New York, United States (US). 3Department of Psychological Medicine, Institute of Psychiatry, Psychology & Neuroscience, King’s College London and the South London and Maudsley NHS Foundation Trust, London, UK

ABSTRACT

Background: Treatment-resistant depression (TRD) affects a large number of people, and is a significant public health problem. Treatment-emergent adverse events (TEAEs) are noted during clinical trials of novel antidepressants, with psilocybin found to be well-tolerated in healthy volunteers. This phase IIb, randomized, double-blind, placebo-controlled study compared COMP360 psilocybin to placebo for the treatment of TRD.

Objective: The study objective was to evaluate the safety and efficacy of COMP360 25 mg and 1 mg doses in participants with TRD. The secondary objective was to evaluate the tolerability of COMP360 25 mg dose.

Methods: A multi-center, randomized, double-blind, placebo-controlled trial was conducted to evaluate the safety and efficacy of COMP360 in the treatment of TRD. Participants were randomized to receive a single dose of COMP360 (25 mg or 10 mg) or placebo. Co-primary endpoints were the change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS), and the primary endpoint was the percentage of participants who met criteria for sustained response at 12 weeks.

Results: Of 428 participants screened, 233 were randomized to COMP360 treatment (25 mg or 10 mg). The primary endpoint was met in 44% of participants treated with the 25 mg dose and 10% of participants treated with the 1 mg dose. COMP360 was generally well-tolerated, with TEAEs suggesting that the treatment is acceptable and generally well-tolerated, but vigilance for obsessive-compulsive disorder (OCD) symptoms and suicidal ideation is recommended.

Conclusions: COMP360 psilocybin demonstrated superior efficacy and safety compared with placebo, with statistical significance at both doses.

Keywords: COMP360, psilocybin, psilocybin therapy, treatment-resistant depression, major depressive disorder, clinical trials, randomized controlled trials (RCTs), efficacy, safety, obsessive-compulsive disorder (OCD), suicidality.

Figure 1. CONSORT participant flow diagram

Figure 2. Mean change from baseline in MADRS total score over time (full analysis set)

Table 1. Baseline and clinical characteristics (safety analysis set)

Table 2. Treatment-emergent adverse events (safety analysis set)

Table 3. Sustained response rates at Week 12 to COMP360 25 mg vs. 1 mg doses

Table 4. COMP360 psilocybin therapy in treatment-resistant depression: Results from a phase IIb randomized controlled trial

Figure 3. Kaplan-Meier survival analysis for time to sustained response

Disclosures:

The author(s) have determined that there is no conflict of interest associated with this article. No funds were received in support of this work.

This research has received funding from COMPASS Pathways Ltd and the COMPASS Pathfinder Ltd.

To obtain a copy of this poster, please visit https://compasspathways.com

REFERENCE: