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First ever psychedelic research presented at ASCO shows positive mental health benefits of psilocybin-assisted therapy for cancer patients

50% of patients reported remission from depression after single dose of psilocybin

BETHESDA, MD (June 2, 2022) – A majority of patients with major depressive disorder (MDD), also known as clinical depression, who received a single 25 mg fixed dose of psilocybin and two group integration sessions had a significant reduction in depression in a feasibility trial presented at the American Society of Clinical Oncology’s Annual Meeting, taking place June 3-7 in Chicago, IL.

The exploratory trial—the first to test the safety and feasibility of simultaneous administration of COMP360, a synthetic psilocybin formulation created by COMPASS Pathways—found 80% of participants had a significant reduction in depression for up to eight weeks, and 50% reported complete remission of depression symptoms for up to eight weeks after treatment with psilocybin.

“While psychedelic-assisted therapy isn’t ready for public use now, the study findings suggest psychedelics could be a powerful tool in treating patients’ mental health,” said Paul Thambi, MD, chief medical officer of Sunstone Therapies and an investigator on the study. “The well-being of patients with cancer involves both the emotional and the physical, but we almost always see amazing innovation in treating the physical aspects of cancer and not the emotional. If psychedelic-assisted therapy proves to be beneficial for healing the emotional side of cancer, it will be a major advance and will offer a much-needed therapy for patients.”

In this phase 2 open label study conducted in a community medical center, 30 patients received individual and group preparatory sessions days prior to treatment with psilocybin. Cohorts of 3-4 patients then received psilocybin and were guided through the 6–8-hour experience by trained therapists. They were also monitored by lead therapists and clinicians via a live video and audio feed to ensure safety and compliance. The following day and one week later, patients participated in group integration sessions, where they engaged in further sharing and psychotherapy occurred.

The research team used the Montgomery-Asberg Depression Rating Scale (MADRS), a clinician-administered, symptom questionnaire scoring the severity of depression from 0 (depressive symptoms absent) to 60 (severe depression), to assess each patient’s mental health. A limitation of the study is risk of bias because this was an open-label study in which neither patients nor raters were blinded.

Critical data points:

- Patients had an average MADRS score of 25.9, representing moderate depression, at baseline

- After psilocybin assisted therapy, the score dropped by an average of 19.1 points
- 24 patients saw a sustained response rate (a decrease of $\geq 50\%$ in the MADRS score from baseline, fulfilled at any visit up to and including week three and also fulfilled at week eight)
- 15 patients showed remission of depression symptoms (a MADRS score < 10) one week after a single dose of psilocybin, which was sustained up to eight weeks

The study was conducted at the Aquilino Cancer Center in the Bill Richards Center for Healing, a space specifically designed for administration of psychedelic therapy, with the help of COMPASS Pathways. This trial was completed in nine months. Dr. Thambi states more study is needed to understand how long remission and symptom reduction were maintained and how many participants resumed psychiatric medication use. A long term follow-up study is planned to address these questions.

About Maryland Oncology Hematology and the Aquilino Cancer Center

Maryland Oncology Hematology is the largest independent cancer physician practice in Maryland, with more than 30 doctors in nine locations. Its Rockville location is part of the Aquilino Cancer Center, a state-of-the-art outpatient community cancer center promoting physical, mental and spiritual healing for people at all stages of their cancer journey, and the first freestanding community cancer center in Montgomery County, Maryland. The Aquilino Cancer Center is a part of the Adventist HealthCare Shady Grove Medical Center campus and offers personalized, coordinated cancer care to patients and their loved ones under one roof in a unique healing environment.

About Sunstone Therapies

Sunstone Therapies is a company committed to accelerating and scaling a high standard of psychedelic therapy in the medical setting by conducting clinical trials, providing training for therapists in the field, learning from experiences and feeding this back into centers to further improve experiences and outcomes for patients. They are creating a network of centers to offer psychedelic therapy for patients suffering from depression, anxiety, and other mental health conditions more broadly.

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