Swiss Medical Society for Psycholytic Therapy (SÄPT) Announces Data Demonstrating Reductions in Anxiety that Persist Through Two Years After Treatment with LSD

-Remission Rates Maintained for One Year After the End of the 50-week Placebo-Controlled Portion of the Study-

-LSD-Assist Study Collaboration Conducted by Investigators from University Hospital Basel (UHB) and SÄPT-

-Updated Results Presented at the Society of Biological Psychiatry (SOBP) Meeting, Original Study Recognized by SOBP With Somerfeld-Ziskind Award for Outstanding Research Investigations in Biological Psychiatry-

AUSTIN, TX – May 13, 2024 – SÄPT today shared new data, presented by researchers this weekend, which showed that long-term efficacy was maintained for almost 2 years among adult patients participating in the LSD-Assist Study that investigated the efficacy and safety of LSD in the treatment of anxiety.

Data presented at the annual meeting of the SOBP in Austin, Texas, demonstrated that 1 year after the conclusion of the 50-week-long placebo-controlled period of the LSD-Assist Study, participants' scores on the clinically validated State-Trait Anxiety Inventory–Global (STAI-G), showed that remission rates remained the same – 32% at week 50 vs. 33% at week 102.

"The statistically significant, rapid, strong and long-lasting reductions in STAI-G scores, combined with similarly sustained responses in all secondary endpoints are extremely encouraging," said Friederike Holze PhD, UHB, who presented the study. "While LSD has shown beneficial effects on reducing anxiety, there has still been a need for a deeper understanding of its long-lasting effects and safety. This is why we designed a robust, randomized, double-blind placebo-controlled clinical trial with a pre-planned long-term follow-up period."

In the 50-week placebo-controlled period of the LSD-Assist study, the primary endpoint was achieved with LSD treatment resulting in statistically significant and robust reductions of STAI-G scores 16 weeks after treatment in the between-subjects analysis

(least square mean (± SE) change from baseline difference = -16.2 (5.8), 95% CI=-27.8 to -4.5, p=0.007). Effects were maximal 2 weeks after the second LSD session and sustained throughout the study.

Acute positive effects or mystical experiences significantly correlated with long-term therapeutic outcomes at 16 weeks. LSD was well-tolerated, with only one SAE that was considered related to treatment, which consisted of acute transient anxiety and delusions during an LSD session with a positive outcome for the patient. There were no recorded instances of treatment-emergent suicidal ideation with intent, suicidal behavior, or intentional self-injury.

About the LSD-Assist Study

This investigator-initiated, two-center, clinical trial was a double-blind, placebo-controlled, cross-over trial that investigated the safety and efficacy of LSD for the treatment of anxiety. The trial enrolled 46 patients either suffering from anxiety symptoms with life-threatening illnesses or with an anxiety disorder without severe somatic illness. Patients were randomly assigned to two sessions, separated by 6 weeks, with either oral LSD (200 µg) or placebo administration in the first period and vice versa after the cross-over in the second period and were initially followed for 50 weeks.

The primary efficacy endpoint was the reduction in anxiety symptoms 16 weeks after the second LSD or placebo administration in the first period. The primary outcome measure was the State-Trait Anxiety Inventory (STAI) global score, which is used to assess the severity of anxiety symptoms. Secondary outcome measures included improvements in Hamilton Depression Scale (HAM-D-21), Beck Depression Index (BDI), and several other major psychiatric symptoms (Symptom-Check-List-90-R) scores. For additional information on this trial see clinicaltrials.gov [NCT03153579].

Long-term Follow-up from LSD-Assist

The long-term data presented at SOBP were based upon an *a priori*-planned long-term follow-up designed to help understand the long-term impact of LSD on participants'

anxiety. Participants were contacted 52 weeks after their last visit from the placebo-controlled study for assessments utilizing the same validated questionnaires administered in previous study visits. This study revealed potential long-lasting benefits from LSD in patients with anxiety, showing sustained improvements in anxiety (STAI-G scores) 12 months post-study with no additional adverse effects reported.

"We are pleased to see the results from this study persist for the participants in this trial one year after its placebo-controlled portion concluded and are encouraged that they continue to benefit from their treatment," added Peter Gasser, MD, co-investigator of the study and President of SÄPT. "Dr. Holze and I feel honored to receive SOBP's Somerfeld-Ziskind award and thank all the patients whose long-term participation made these findings possible."

About SÄPT, the Swiss Medical Society for Psychedelic Treatment

The Swiss Medical Association for Psycholytic (Psychedelic) Therapy was founded in 1985 and has now developed into a specialist society with around 210 members, primarily from Switzerland and Germany. Its statutory purpose is to make psychoactive substances accessible for practical psychotherapeutic use, to control their handling, to stimulate further research and to offer the theoretical and practical training necessary for their handling. SÄPT has been led by Dr. Gasser since 1997.

From 1988 to 1993, five SÄPT therapists received an exemption from the Swiss Federal Office of Public Health (BAG) to carry out psychedelic treatment with the substances MDMA and LSD in their practices. During these five years, about 170 patients were treated, undergoing just over a thousand full-day sessions, and the results were published in 1996. Since then, SÄPT has conducted or co-sponsored numerous studies and initiated the limited-use program, which has given around 60 therapists the opportunity to treat several hundred patients with psychedelic substances under individual licenses over the last ten years.

Media Inquiries: info@saept.ch