Beckley Psytech announces first cohort dosed in Phase 1 clinical trial assessing safety and tolerability of intranasal 5-MeO-DMT

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- Phase 1 trial is evaluating the safety and tolerability of a novel formulation of intranasal 5-MeO-DMT
- Study will measure detailed pharmacokinetics and metabolism of 5-MeO-DMT in healthy volunteers
- Preliminary data, expected H1 2022, to support Phase 2 study designs investigating the use of 5-MeO-DMT in treatment resistant depression (TRD) and other neuropsychiatric indications

Oxford, United Kingdom – 25 October 2021 - Beckley Psytech, a private company dedicated to addressing neurological and psychiatric disorders through the novel application of psychedelic medicines, announced that the first cohort of volunteers has been dosed in a clinical trial exploring the safety of Beckley Psytech's novel formulation of intranasal 5-Methoxy-N,N-Dimethyltryptamine (5-MeO-DMT).

The Phase 1 study is designed as a double-blind, randomised, single ascending dose study to evaluate the safety and tolerability of a single intranasal dose of 5-MeO-DMT in psychedelic-naïve healthy subjects. This is the first clinical study to measure the pharmacokinetics and metabolism of 5-MeO-DMT delivered intranasally.

The study will recruit up to 42 participants (dependent on response) in 6 cohorts of 7 volunteers on increasing doses of 5-MeO-DMT. Blinded data from the study will be used to inform the planned Phase 2 study dose and design in H1 2022. The trial is being conducted as part of Beckley Psytech's ongoing collaboration with King's College London and is being led by Dr James Rucker.

James Rucker, Clinician Scientist and Principal Investigator of the study, the Institute of Psychiatry, Psychology & Neuroscience at King's College London, said: *"We are pleased to be working with Beckley Psytech and to have initiated this study to evaluate the safety and tolerability of 5-MeO-DMT. TRD is a challenging condition to treat, and it is exciting to be exploring new treatment options that could have a positive impact on patients' lives in the future."*

Cosmo Feilding Mellen, CEO of Beckley Psytech, said: *"The start of this Phase 1 study is hugely exciting for Beckley Psytech and for our continued collaboration with Dr James Rucker and his team at King's College London. This trial will provide invaluable information about our novel intranasal formulation of 5-MeO-DMT, and we are looking forward to the readout in 2022. Following this trial, we intend to initiate a Phase 2 study in TRD, a condition with a significant unmet medical need. This is another key milestone achieved on our path to deliver on our clinical pipeline."*

Phase 1 study overview

The Phase 1 study is a double-blind, randomized, single ascending dose trial, with psychedelic-naïve subjects. The study will enrol up to 42 volunteers to evaluate the safety, tolerability, and pharmacokinetics of single ascending intranasal doses of 5-MeO-DMT. The trial will also look to characterise the psychedelic experience of the subjects, with interviews carried out by a specialist.

More information about the trial is available on www.clinicaltrials.gov (NCT05032833)