



Beckley Psytech launches Phase IIa study of lead candidate BPL-003, a novel benzoate formulation of 5-MeO-DMT, for Treatment Resistant Depression

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Oxford, United Kingdom – 21 DECEMBER 2022 - Beckley Psytech, a private, clinical-stage biotechnology company dedicated to addressing neuropsychiatric conditions through the novel application of psychedelic medicines, today announced that it had initiated a Phase IIa study investigating BPL-003, a proprietary intranasal formulation of synthetic 5-Methoxy-N, N-Dimethyltryptamine (5-MeO-DMT), for Treatment Resistant Depression (TRD).

Depression affects around [280 million people around the world](#), but [30% of those living with the condition](#) are resistant to available antidepressant medications, meaning there is an urgent need for more effective treatments. Beckley Psytech's Phase IIa study ([NCT05660642](#)), taking place at King's College Hospital and Hammersmith Medicines Research, will explore the effects of a single dose of BPL-003, in combination with psychological support, in TRD patients with moderate to severe symptoms who are not taking concomitant antidepressants.

Patients will be followed for 12 weeks after initial dosing, with safety, pharmacokinetic and efficacy assessments conducted at multiple points throughout that period. The first patient is expected to be enrolled in January 2023.

Dr. James Rucker, Consultant Psychiatrist and Senior Clinical Lecturer, leads the Psychoactive Trials Group at King's College London and is the Principal Investigator of the trial. He said: *"Having been a part of Beckley Psytech's successful Phase I studies of 5-MeO-DMT, we are looking forward to exploring the safety, tolerability and efficacy of intranasal BPL-003 in further clinical trials with those suffering with Treatment Resistant Depression. These studies will inform the development pathway for BPL-003 in this common and devastating mood disorder."*

A second exploratory study, investigating the effects of a single-dose of BPL-003 alongside abstinence-oriented cognitive behavioural support in people suffering with Alcohol Use Disorder, is also expected to be initiated in early 2023.

Cosmo Feilding Mellen, CEO of Beckley Psytech, said: *"Conditions like Treatment Resistant Depression have a devastating effect on people around the world, but they are sadly underserved when it comes to treatment opportunities. We are proud to be conducting rigorous scientific investigations into the therapeutic potential of novel, short-acting psychedelic compounds like BPL-003 to help people in urgent need and we are looking forward to dosing the first patient in the coming weeks. I would like to take this opportunity to thank not only our research partners at King's and HMR for their support and collaboration, but also the many healthy volunteers and future patients that participate in our trials and are willing to contribute to our research program. We at Beckley Psytech are all single-mindedly focussed on the wellbeing of patients and are grateful for their willingness to participate in clinical research."*

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About Beckley Psytech - www.becklepsytech.com

Beckley Psytech Ltd is a private, clinical-stage biotechnology company dedicated to improving the lives of people suffering from neuropsychiatric disorders by developing a pipeline of psychedelic compounds into licensed pharmaceutical medicines. The Company's most advanced programmes are focused on the development of BPL-003, an intranasal synthetic formulation of 5-MeO-DMT, for treatment resistant depression (TRD) and ELE-101, an intravenous synthetic formulation of psilocin, the active metabolite of psilocybin, for major depressive disorder (MDD). Founded in 2019, and underpinned by more than two decades of pioneering scientific research from the Beckley Foundation, Beckley Psytech combines world-leading psychedelic science with deep drug development expertise in order to optimise patient outcomes, improve treatment opportunities and ease the burden these conditions have on individuals and society.