



## First patient dosed in Beckley Psytech's Phase IIa study of BPL-003 for Treatment Resistant Depression

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**Oxford, United Kingdom – 04 MAY 2023** - Beckley Psytech Ltd, a private, clinical-stage biotechnology company dedicated to addressing neuropsychiatric disorders by transforming psychedelics into effective and licensed medicines, announced today that the first patient has been dosed in its Phase IIa study evaluating BPL-003 as a potential therapy for Treatment Resistant Depression (TRD). BPL-003 is Beckley Psytech's novel synthetic formulation of the psychedelic compound 5-MeO-DMT (also known as Mebufotenin) and is administered intranasally via an FDA-approved delivery device.

[Phase I data](#) has already shown BPL-003 to be well-tolerated with consistent dose delivery and a reproducible, dose-proportional pharmacokinetic profile. Medium and high dosages were found to reliably induce profound psychedelic experiences (a correlate of positive clinical outcomes) with a rapid onset and timely offset (60 - 90min.) of psychedelic treatment effects.

Beckley Psytech's open-label Phase IIa study ( [NCT05660642](#)), currently recruiting at King's College London and Hammersmith Medicines Research, has been designed to evaluate the safety, efficacy and pharmacokinetics of a single dose of BPL-003, in combination with psychological support, in patients with moderate to severe TRD 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.

Topline results are expected in 2023 and will be used alongside data from Beckley Psytech's global multi-site Phase IIb study of BPL-003 in patients with TRD to inform the future clinical development of BPL-003. Beckley Psytech received the Food and Drug Administration's (FDA) first ever [Investigational New Drug \(IND\) approval](#) for a Phase IIb clinical trial of a short-acting psychedelic in February 2023. The study, which is taking place at 40 investigator sites across 7 different countries, will evaluate the effects of a single medium or high dose of BPL-003 against a sub-perceptual dose in patients with moderate to severe TRD who are not taking concomitant antidepressants. Initial results from that study are expected in 2024.

**Commenting on the first patient dose, Dr Rob Conley, Chief Scientific Officer at Beckley Psytech, said:** "Dosing the first patient in this study is hugely exciting, and we are looking forward to exploring the potential therapeutic effects of BPL-003 for patients living with Treatment Resistant Depression. Around one third of all people living with depression are resistant to currently available antidepressants and there is an urgent need for more effective treatments. We are proud to be leading the way in developing alternative therapies that are safe, effective and practical and we hope to have more to share soon."

For more information please contact: Charlotte Chorley, Communications Lead at [info@becklepsytech.com](mailto:info@becklepsytech.com)

**About Beckley Psytech - [www.becklepsytech.com](http://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 transforming psychedelics into effective and licensed medicines. The company's most advanced programmes are focused on the development of psychedelic-based medicines to treat people with Treatment Resistant Depression (TRD), Alcohol Use Disorder (AUD) and 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 extensive drug development expertise in order to optimise patient outcomes, improve treatment opportunities and ease the burden neuropsychiatric conditions have on individuals, healthcare systems and society.