Draig Therapeutics Announces US FDA Clearance of IND Application for Phase 2 Study of DT-101 for the Treatment of Major Depressive Disorder

- DT-101 is designed to allow effective modulation of the AMPA receptor without compromising safety
- Phase 2 clinical trial initiation anticipated before the end of 2025
- Trial builds on positive Phase 1 study that showed DT-101 was well tolerated and demonstrated target engagement

Cardiff, United Kingdom – 2 October 2025 – Draig Therapeutics ("Draig"), a clinical-stage company aiming to transform the treatment of neuropsychiatric diseases, today announces that it will initiate a Phase 2 study of DT-101, a next-generation AMPA receptor positive allosteric modulator (PAM) for Major Depressive Disorder (MDD) in the US in Q4 2025. The decision follows US Food and Drug Administration (FDA) clearance of the IND application for the Phase 2 trial protocol.

Ruth McKernan, Interim CEO and founder of Draig Therapeutics, said: "Initiating our Phase 2 study with DT-101 under a US IND is an important milestone for Draig. This achievement highlights the rapid progress we've made following the closing of our highly successful Series A financing round in June 2025 and advances our mission to bring innovative treatments to people suffering from neuropsychiatric disorders."

Inder Kaul, MD, Chief Medical Officer at Draig Therapeutics, added: "Millions of people worldwide are living with the debilitating effects of depression, and a large proportion of these individuals either do not respond to or cannot tolerate available antidepressants. This fact clearly underscores the urgent need for new options that provide meaningful and sustained relief. The data Draig has already generated on DT-101 provide a robust foundation for this Phase 2 trial, which has been designed to investigate clinical efficacy and safety of DT-101 in people with MDD."

The Phase 2 "TARIAN-1*" study is a multi-centre, randomised, double-blind, placebo-controlled, trial in people with MDD and aims to enrol more than 300 participants. The trial is expected to start initially in the US and then will expand to clinical sites in the UK and selected countries in the European Union pending relevant regulatory authorisations. The TARIAN-1 study will evaluate the safety and efficacy of DT-101 in people with MDD compared to placebo and the primary endpoint is change in the participants' score of the Montgomery Åsberg depression rating scale (MADRS). Draig anticipates reporting topline data from the trial in the second half of 2027.

The Phase 2 trial builds on the positive results from a completed Phase 1 programme in over 60 subjects, in which DT-101 was found to be well tolerated and demonstrated target engagement using the novel technique of magnetoencephalography. Data from the Phase 1 programme will be presented at a future scientific meeting.

In June 2025, Draig announced that it raised $140 million to fund clinical studies related to DT-101 in MDD and to advance DT-201 and DT-301, two highly selective $GABA_A$ receptor modulators into

clinical development in 2026, with the goal of demonstrating their best-in-class potential across a range of prevalent and underserved neuropsychiatric disorders.

**TARIAN is the Welsh word for 'shield'*, which reflects the underlying objective of this trial – to protect individuals from the debilitating effects of depression.

More information about MDD can be found on our website: www.draigtherapeutics.com

ENDS

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About Draig Therapeutics
Draig Therapeutics is a clinical-stage company with a mission to transform treatments in Neuropsychiatry. The company is leveraging its founders' unique scientific expertise in modulating the core glutamate / GABA pathways that play a critical role in neuropsychiatric diseases to advance a pipeline of groundbreaking therapies designed to address large unmet patient needs, including in Major Depressive Disorder (MDD).

Draig is the Welsh word for 'dragon' and it reflects the company's origins in Wales. The name and logo were inspired by this heritage, reflecting its scientific roots stemming from Cardiff University.

Draig was co-founded by Cardiff University and SV Health Investors, which led the seed financing with ICG, and is backed by other leading healthcare venture firms including Access Biotechnology, Canaan Partners, SR One, Sanofi Ventures and Schroders Capital. For more information, please visit www.draigtherapeutics.com