Newleos Announces Dosing of First Participant in U.K. Phase 1b Study of NTX-1955 in Generalized Anxiety Disorder

BOSTON – April 1, 2026 – Newleos Therapeutics, Inc., a clinical-stage biotechnology company developing innovative treatments for neuropsychiatric disorders, today announced that the first participant has been dosed in the company's third Phase 1b study of NTX-1955, designed to evaluate its safety and tolerability in generalized anxiety disorder (GAD). NTX-1955 is Newleos' $GABA_A$-γ1 positive allosteric modulator (PAM) and represents a potential first-in-class treatment for GAD. The Phase 1b study is a multi-center randomized, double-blind, placebo-controlled trial being conducted in the U.K. in adults with GAD. The company previously announced the initial dosing of participants in two other Phase 1b trials being conducted in the EU in July and September 2025. Data from these three Phase 1b studies are expected to inform the dose selection and design of a Phase 2 efficacy study of NTX-1955.

"Generalized anxiety disorder remains one of the most undertreated conditions in psychiatry, and the limitations of current pharmacological options are well documented," commented Sanjay Mathew, M.D., Professor and Department Head, Department of Psychiatry & Behavioral Sciences, Texas A&M University Naresh K. Vashisht College of Medicine, and member of Newleos' clinical advisory board. "I'm encouraged to see Newleos advance this program in robust Phase 1b studies and look forward to seeing what this novel mechanism can offer patients."

"Unlike traditional therapeutic approaches like SSRIs and benzodiazepines, our product candidate is designed to precisely target the neural circuits that drive anxiety," noted Federico Bolognani, M.D., Ph.D., Newleos' Co-founder and Chief Medical Officer. "This clinical milestone brings us one step closer to our goal of improving upon treatment options for patients with generalized anxiety disorder. We look forward to presenting the results of these three Phase 1b studies at upcoming industry meetings."

The Phase 1b study is actively enrolling participants in the U.K. ages 18 to 55 years with current diagnoses of GAD, as defined by the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) and confirmed by Mini-International Neuropsychiatric Interview (MINI). Participants are randomized to receive NTX-1955 (at one of two possible dose levels) or matched placebo once daily for two weeks and will visit the clinic six times over the course of the six-week study period, inclusive of screening and follow up visits. The primary endpoint for the study is the safety and tolerability of NTX-1955 measured by the incidence and severity of treatment-emergent adverse events (TEAEs) over the course of the study period. The trial also includes pharmacokinetic measures of plasma concentrations of NTX-1955 as secondary endpoints and quantitative electroencephalography (qEEG) measures to inform NTX-1955's pharmacodynamic effects as exploratory endpoints. Additional information on the Phase 1b study is available on the U.K.'s clinical study registry: https://www.isrctn.com/ISRCTN18346744

About Generalized Anxiety Disorder (GAD)

GAD is the second most common mental health disorder among adults (approximately 20 million adults in U.S. alone). GAD is characterized by restlessness, irritability, feeling on edge, being easily startled, and panic attacks. GAD can also be characterized by physical ailments such as muscle tension, fatigue, irritability, gastrointestinal symptoms, and headaches. A substantial proportion of GAD patients remain inadequately managed by approved pharmacological therapies such as selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs) and benzodiazepines. Specifically, while first-line SSRIs and SNRIs are ineffective in roughly half of all patients, second-line benzodiazepines, while highly efficacious, are not recommended for long-term use due to sedation, potential for misuse and dependence, and cognitive impairment.

About NTX-1955

NTX-1955 is a potential first-in-class $GABA_A$-γ1 positive allosteric modulator (PAM). $GABA_A$ is the major inhibitory neurotransmitter in the brain and positive allosteric modulation of the $GABA_A$ receptor is a well-validated approach for managing GAD symptoms. Nonselective $GABA_A$ PAMs such as benzodiazepines, while robust anxiolytics, modulate $GABA_A$ receptors throughout the entire brain, including in brain regions that lead to cognitive and sedative side effects. In contrast, NTX-1955 is designed to selectively engage GABAergic transmission in the amygdala, which is at the center of the brain's regulation of anxiety and highly enriched for the $GABA_A$-γ1 receptor subunit, thereby sparing brain networks associated with the safety liabilities of benzodiazepines. Newleos is currently conducting two Phase 1b studies in the European Union (EU) and one in the U.K. to assess the pharmacology and proof-of-mechanism for NTX-1955 in GAD. NTX-1955 has shown dose-dependent anxiolytic activity in several gold-standard preclinical models used in anxiety research matching benzodiazepines' efficacy without the side effect profile seen with classical benzodiazepines. Further, NTX-1955 has completed multiple Phase 1 studies, including Single Ascending Dose, Multiple Ascending Dose, drug-drug interaction, and receptor occupancy studies, demonstrating that it is safe, well tolerated, brain penetrant and selective to $GABA_A$-γ1.

About Newleos Therapeutics

Newleos Therapeutics is dedicated to providing a new dawn or "eos" for the one in every eight people around the world who are suffering from mental illness. The company's pipeline was licensed from Roche and focuses on innovative neuropsychiatric mechanisms of action that aim to reduce side effects and improve outcomes compared to the current standard of care. Newleos' clinical-stage, oral small molecules target $GABA_A$-γ1, V1a, TAAR1 and $GABA_A$-α5, with first- or best-in-class potential in the treatment of general anxiety, social anxiety, substance use disorders, and cognitive impairment. Newleos launched in 2025 with an oversubscribed $93.5 million Series A financing led by Goldman Sachs Alternatives with participation from Novo Holdings A/S, Longwood Fund, DCVC Bio, and Arkin Bio Capital.

For more information visit www.newleos.com.

Media Contact:
Kari Watson

617-470-8388
media@newleos.com