Newleos Therapeutics Announces Clinical Progress Across Neuropsychiatric Pipeline

– First subject dosed in second Phase 1b clinical study in the European Union assessing the anxiolytic and CNS pharmacological effects of NTX-1955 –

– FDA cleared IND for initiation of a U.S. Phase 2 clinical study of NTX-1472, a novel vasopressin 1a (V1a) receptor antagonist, in adults with social anxiety disorder (SAD) –

BOSTON – September 30, 2025 – Newleos Therapeutics, Inc., a clinical-stage biotechnology company developing innovative treatments for neuropsychiatric disorders, today announced that the first subject has been dosed in the company's second Phase 1b study of NTX-1955 in the European Union (EU). NTX-1955 is a $GABA_A$-γ1 positive allosteric modulator (PAM) and represents a novel approach for the treatment of generalized anxiety disorder (GAD). The company announced the initiation of dosing in the first Phase 1b study of NTX-1955 in the EU in July 2025.

Newleos also announced today that the U.S. Food and Drug Administration (FDA) cleared its Investigational New Drug (IND) application for a Phase 2 study of NTX-1472, the company's novel vasopressin 1a (V1a) receptor antagonist for the treatment of social anxiety disorder (SAD). The company plans to initiate a randomized, double-blind, placebo-controlled Phase 2 study at multiple centers in the U.S. to assess the safety, tolerability and efficacy of NTX-1472 in adults with SAD.

"I am extremely proud of the significant clinical and regulatory progress that Newleos has achieved in the short time since our launch earlier this year," said David Donabedian, Ph.D., Founding Chief Executive Officer at Newleos and Executive Partner at Longwood Fund. "With NTX-1955 advancing in two Phase 1b studies and FDA clearance to begin a Phase 2 study of NTX-1472, we are making meaningful strides toward our mission of delivering next-generation pharmacotherapies to the millions of patients living with anxiety disorders who remain underserved by existing treatments."

Federico Bolognani, M.D., Ph.D., Co-Founder and Chief Medical Officer at Newleos, commented, "These are critical milestones for Newleos, for anxiety patients and for the clinical validation of our novel oral therapies targeting $GABA_A$-γ1 and V1a receptors. Existing treatments for both GAD and SAD are severely limited due to their undesirable side effects, and pharmacologic treatment is an integral part of a comprehensive treatment plan for patients suffering from anxiety disorders. We look forward to presenting initial results from our ongoing clinical studies of NTX-1955 at upcoming industry meetings and proceeding with the initial dosing of SAD patients in our Phase 2 study of NTX-1472."

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. Most GAD patients are poorly 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 most 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 first-in-class $GABA_A$-γ1 positive allosteric modulator (PAM). Newleos licensed NTX-1955 from Roche and is currently conducting two Phase 1b studies in the European Union (EU) to assess the pharmacology and proof-of-mechanism for NTX-1955 in Generalized Anxiety Disorder (GAD). $GABA_A$ 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. 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 Social Anxiety Disorder (SAD)

Approximately 20 million adults in the U.S. are diagnosed with SAD every year, totaling approximately 7.1% of the population. SAD is characterized by fear, anxiety and avoidance that interferes with relationships, daily routines, work, school or other activities. SAD is more common among teens and adolescents, with higher prevalence among females. Many patients and caregivers feel currently available treatment options fall short due to lack of efficacy, unwanted side effects and potential for addiction.

About NTX-1472

NTX-1472 is a best-in-class, highly selective, brain-penetrant vasopressin 1a (V1a) receptor antagonist. Newleos licensed NTX-1472 from Roche and plans to initiate a Phase 2 study in the U.S. to assess the safety, tolerability and efficacy of NTX-1472 in adults with social anxiety disorder (SAD). V1a is the receptor for arginine vasopressin (AVP), a neuropeptide that modulates amygdala activation in response to threatening stimuli and anxious moods. V1a receptors are expressed at high levels in multiple regions of the brain that modulate social behaviors and anxiety, such as the central amygdala, lateral septum, and bed nucleus of the stria terminalis. NTX-1472 has completed multiple Phase 1 studies, including Single Ascending Dose, Multiple Ascending Dose, and drug-drug interaction studies and was found to be safe and well tolerated.

About Newleos Therapeutics, Inc.
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 was co-founded by Longwood Fund, Federico Bolognani, M.D., Ph.D., and William Martin, Ph.D., seasoned experts in company creation and CNS drug development.

For more information visit www.newleos.com.

Media Contact:
Kari Watson
617-470-8388
media@newleos.com