Newleos Therapeutics Announces Dosing of First Participant in SOAR Phase 2 Study of NTX-1472 for Social Anxiety Disorder

BOSTON – January 6, 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 SOAR (SOcial Anxiety Reduction) Phase 2 study of NTX-1472, the company's novel vasopressin 1a (V1a) receptor antagonist, which is being developed for the treatment of social anxiety disorder (SAD). SOAR is a randomized, double-blind, placebo-controlled, multi-center Phase 2 study designed to assess the safety, tolerability, and efficacy of NTX-1472 in adults with SAD.

"Advancing two novel anxiety product candidates – NTX-1955 and now NTX-1472 – to the next stages of clinical development in under a year since the launch of Newleos is a tremendous achievement that underscores the passion and technical excellence of our team," said Tim Noyes, Chief Executive Officer of Newleos. "We are excited to rapidly progress these two programs that could address the significant unmet medical needs of anxiety patients who remain underserved by existing treatments."

"General and social anxiety disorders affect millions of people worldwide, yet existing therapies often provide limited symptom relief and are constrained by safety and tolerability challenges," noted Federico Bolognani, M.D., Ph.D., Newleos' Co-founder and Chief Medical Officer. "Both NTX-1955 and NTX-1472 are designed to precisely target the neural circuits that drive anxiety, setting them apart from traditional therapeutic approaches. Together, these programs have the potential to expand and improve upon treatment options for patients with anxiety disorders."

The SOAR Phase 2 study is actively enrolling participants ages 18 to 65 years with current diagnoses of SAD, generalized subtype, as defined by the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) and confirmed by the Structured Clinical Interview for DSM-5. Participants will be randomized to receive NTX-1472 or matched placebo once daily for eight weeks. The primary endpoint is the incidence and severity of treatment-emergent adverse events. Secondary endpoints include the change in clinician-administered Liebowitz Social Anxiety Scale (LSAS) scores over the study period compared to baseline measurements. Additional information on the SOAR Phase 2 study will be available on www.ClinicalTrials.gov.

About Social Anxiety Disorder (SAD)

SAD is a common and chronic anxiety disorder affecting approximately 15-20 million adults in the U.S. SAD has two primary subtypes: generalized SAD, characterized by pervasive fear, anxiety and avoidance across a wide range of social situations, and performance-only SAD, in which symptoms are limited to specific performance-based situations such as public speaking. Across subtypes, SAD is characterized by intense fear of negative evaluation, anticipatory anxiety, panic symptoms, and avoidance behaviors that interfere with daily functioning. SAD can also manifest with physical symptoms such as blushing, trembling, sweating, gastrointestinal distress, and tachycardia. A substantial proportion of patients with

generalized SAD remain inadequately managed by available pharmacological therapies, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs). These first-line serotonergic therapies are ineffective or poorly tolerated in many patients, and treatment is often limited by side effects such as emotional blunting and sexual dysfunction, contributing to underuse, discontinuation, and persistent unmet need.

About NTX-1472

NTX-1472 is a potential best-in-class, highly selective, brain-penetrant vasopressin 1a (V1a) receptor antagonist. V1a is a receptor of arginine vasopressin (AVP), a neuropeptide that plays a key role in modulating anxiety and stress. V1a receptors are highly expressed in regions of the brain that are essential for social and threat processing, such as the lateral septum, central amygdala, and bed nucleus of the stria terminalis. Newleos is currently conducting the Phase 2 SOAR study, a randomized, double-blind, placebo-controlled, multi-center study designed to assess the safety, tolerability, and efficacy of NTX-1472 in adults with SAD. 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 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) 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 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. 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.

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