Newleos Announces $15.5 Million NIH Grant and Receipt of FDA Fast Track Designation for NTX-2001 to Treat Substance Use Disorders

– Five-Year National Institute on Drug Abuse (NIDA) grant expected to fund NTX-2001 development in cocaine use disorder through Phase 2 efficacy studies –

– Fast Track designation granted for NTX-2001 in alcohol use disorder –

BOSTON – November 3, 2026 – Newleos Therapeutics, Inc., a clinical-stage biotechnology company developing innovative treatments for neuropsychiatric disorders, today announced that the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), has awarded the company up to $15.5 million to fund the development of NTX-2001 in cocaine use disorder (CUD). NTX-2001 is the company's novel partial agonist of trace amine-associated receptor 1 (TAAR1), which is being developed as a potential first-in-class therapeutic for substance use disorders, including alcohol use disorder (AUD) and CUD. The five-year, milestone-based grant, which is Newleos' first federal grant, funds the development of NTX-2001 through a Phase 1 drug-drug interaction study and a subsequent Phase 2 efficacy study. The funds were awarded based on strong preclinical evidence supporting a clear mechanistic rationale for NTX-2001 in treating CUD, along with its validated safety and tolerability profile in humans.

Newleos also announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to NTX-2001 for the treatment of AUD. The FDA's Fast Track process is designed to deliver important new medicines to patients more quickly, facilitating the development and expediting the review of therapies intended to treat serious conditions and address unmet medical needs. Products granted Fast Track designation are eligible for more frequent interactions with the FDA during clinical development and potentially accelerated approval and/or priority review.

"Cocaine use disorder is a serious, growing public health crisis with no FDA-approved pharmacotherapies available today, and this NIDA award provides funding to advance NTX-2001 through Phase 2 studies," said Federico Bolognani, M.D., Ph.D., Newleos' Co-founder and Chief Medical Officer. "In parallel, the FDA's Fast Track designation for NTX-2001 in alcohol use disorder reflects the significant unmet need in AUD and will allow for more frequent interactions with the agency as we advance our ongoing Phase 1b study, with topline data expected in the first half of 2027. We're grateful for NIDA's support and look forward to our continued collaboration with FDA as we work to bring this therapy to patients in need as rapidly as possible."

About NTX-2001

NTX-2001 is a selective partial agonist of the trace amine-associated receptor 1 (TAAR1) currently in development for alcohol use disorder (AUD) with planned studies in cocaine use disorder (CUD) supported by a grant from NIDA. TAAR1 is a G protein-coupled receptor expressed in key brain regions that modulate dopaminergic circuits, including reward reinforcement and satiety. Consistent with expression patterns of TAAR1, NTX-2001 has been shown to modulate dopaminergic neurotransmission in the midbrain-nucleus accumbens reward circuit. TAAR1 agonism acts by normalizing dopaminergic neurotransmission in a state-dependent manner, thereby reducing excessive or increasing insufficient dopamine signaling. TAAR1 activation modulates dopamine neurotransmission in addiction circuits, leading to the inhibition of the rewarding and reinforcing effects of drugs from different classes, including psychostimulants, opioids, and alcohol.

Newleos is currently conducting a Phase 1b proof-of-concept study in the U.S. to determine the effects of NTX-2001 on alcohol consumption compared to placebo in the alcohol drinking paradigm (ADP), a well-established, translational paradigm to simulate alcohol consumption, among other quantitative measures of drinking behavior. The study will also assess the safety, tolerability, and pharmacokinetics of NTX-2001 in individuals with AUD. Additional information on the Phase 1b study is available on www.ClinicalTrials.gov.

NTX-2001 was previously studied in multiple clinical trials designed to assess the efficacy, safety, tolerability, pharmacokinetics, and pharmacodynamics of multiple formulations of NTX-2001 at multiple dosing regimens. Across all these studies, NTX-2001 was consistently safe and well tolerated.

About Cocaine Use Disorder

CUD is a major and escalating public health crisis in the United States, with over 1.4 million adults meeting the diagnostic criteria for CUD and overdose deaths involving cocaine increasing more than sixfold between 2010 and 2023. CUD is characterized by the compulsive use of cocaine despite its medical, psychological, and behavioral consequences. Cocaine's primary mechanism of action, potent blockade of the dopamine transporter, leads to supraphysiologic accumulation of extracellular dopamine in reward-related regions of the brain. This intense and repeated dopaminergic stimulation drives compulsive use that is difficult to reverse through behavioral intervention alone. Despite decades of research, there are currently no FDA-approved pharmacotherapies for CUD, and existing behavioral treatments such as contingency management and cognitive-behavioral therapy are only moderately effective and are limited by poor adherence. There is an urgent need for a safe, effective, and mechanistically targeted pharmacological treatment for CUD that can reduce cocaine use and cravings without disrupting normal dopamine function in the brain.

About Alcohol Use Disorder

AUD affects nearly 30 million people in the U.S. and is associated with more than 95,000 deaths each year, making it one of the leading preventable causes of death. AUD is characterized by compulsive alcohol consumption, where persistent, compulsive behaviors result in life-threatening medical consequences. The underlying neuropathology of AUD includes dysregulated dopamine signaling (exaggerated dopamine release and impaired control of mesolimbic circuits), and aberrant neurocircuitry signaling satiety. Despite the prevalence and burden of AUD, fewer than 10 percent of those with AUD receive any form of treatment. There are only three FDA-approved pharmacotherapies to treat AUD, and these drugs are only moderately effective and thus limited in their use. There is an urgent need for novel, mechanistically targeted treatments that can more effectively reduce alcohol consumption and cravings while minimizing side effects.

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 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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