Newleos Announces Dosing of First Participant in Phase 1b Study of NTX-2001 for Alcohol Use Disorder

BOSTON – April 29, 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 its Phase 1b study of NTX-2001, 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 alcohol use disorder (AUD). The Phase 1b study is a randomized, double-blind, placebo-controlled clinical trial conducted in collaboration with Yale School of Medicine to measure reductions in alcohol consumption and cravings within an observational setting, as well as safety, tolerability and pharmacokinetics of NTX-2001 in individuals with AUD.

"With the last drug approval for alcohol use disorder nearly two decades ago, the urgency for novel, efficacious pharmacotherapeutic interventions could not be greater," noted Stephanie O'Malley, Ph.D., clinical advisor to Newleos. "There is mounting evidence across addictive disorders, including AUD, that supports the biological rationale for TAAR1 agonists. I am optimistic about the opportunity that this drug class presents and pleased to be collaborating with the Newleos team as they advance this important clinical study."

"As the first time a TAAR1 partial agonist has been evaluated in the clinic for alcohol use disorder, this study of NTX-2001 represents an important milestone for Newleos and for the field of addiction medicine," commented Federico Bolognani, M.D., Ph.D., Newleos' Co-founder and Chief Medical Officer. "TAAR1 partial agonists are well-suited as potential treatments for alcohol use disorder by modulating reward pathways in the brain. Demonstrating early signs of efficacy in this NTX-2001 study would provide clinical support that the TAAR1 mechanism may reduce alcohol use in individuals with AUD. Because addiction almost always involves dopamine dysregulation, success in this Phase 1b study would also be a critical first step in the development of a drug that could treat a wider array of addictive disorders."

The launch of Newleos' Phase 1b study builds on robust preclinical and clinical data supporting the TAAR1 mechanism and NTX-2001 specifically. NTX-2001 was previously studied in eight clinical trials involving healthy volunteers and individuals with schizophrenia or schizoaffective disorder designed to assess efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics. NTX-2001 was studied in multiple formulations at multiple dosing regimens, with approximately 645 participants receiving the study intervention (either NTX-2001 or placebo). Across all these studies, NTX-2001 was consistently safe and well tolerated.

Newleos' Phase 1b study is actively enrolling participants ages 21 to 60 years with current diagnoses of AUD, as defined by the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) and confirmed by Mini-International Neuropsychiatric Interview (MINI). Participants will be randomized to receive NTX-2001 or matched placebo once daily for approximately two weeks and will visit the clinic

four times over the course of the approximately 10-week study period, inclusive of screening and follow-up. The primary endpoint of the study is the number of drinks consumed during the alcohol drinking paradigm (ADP), an established human laboratory analogue designed to simulate drinking behavior. Secondary endpoints include the incidence and severity of treatment-emergent adverse events (TEAEs), vital sign measurements and laboratory test results collected throughout the study, in each case compared to baseline measurements.

Additional information on the Phase 1b study is available on www.ClinicalTrials.gov.

About Alcohol Use Disorder (AUD)

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 NTX-2001

NTX-2001 is a selective partial agonist of the trace amine-associated receptor 1 (TAAR1) in development for alcohol use disorder (AUD). 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.

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.

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