Newleos Therapeutics Appoints Stephen Brannan to Board of Directors and Announces NTX-1955 Clinical Progress in Generalized Anxiety Disorder

- Prominent leader in neuroscience and neuropsychiatric drug development and former CMO of Karuna Therapeutics joins Newleos Board of Directors -

- Newleos to initiate pharmacology and proof-of-mechanism Phase 1b clinical studies of NTX-1955 in generalized anxiety disorder -

BOSTON – July 23, 2025 – Newleos Therapeutics, Inc., a clinical-stage biotechnology company developing innovative treatments for neuropsychiatric disorders, today announced the appointment of Stephen (Steve) Brannan, M.D., to its Board of Directors. Dr. Brannan is an expert in neuroscience and neuropsychiatric drug development with a proven track record of developing innovative medicines through regulatory approval and commercialization. Most recently, he served as Chief Medical Officer at Karuna Therapeutics (acquired by Bristol Myers Squibb in 2024 for $14 billion) where he led the clinical strategy for KarXT (xanomeline–trospium), the first new mechanism of action for schizophrenia approved in over 30 years.

Newleos also announced the filing of clinical trial applications (CTAs) with the competent health authorities for two Phase 1b studies of NTX-1955 to be conducted in the European Union (EU). Dosing has already commenced for one of the studies. Both studies will utilize a well-established, controlled, and reproducible clinical model to assess the anxiolytic effects of NTX-1955, as well as other tests designed to measure a wide range of central nervous system (CNS) effects in a pharmacological context.

“We are thrilled to welcome Steve to the Newleos Board of Directors,” said David Donabedian, Ph.D., Founding Chief Executive Officer of Newleos Therapeutics and Executive Partner at Longwood Fund. “Steve brings an extraordinary track record in neuroscience drug development, having led the clinical strategy behind one of the most significant CNS breakthroughs of the past decade. His expertise in designing rigorous, patient-centered trials and navigating a variety of development paths will be invaluable as we initiate clinical studies for NTX-1955 in anxiety and begin to generate data across our pipeline more broadly. We look forward to his insights as we work to deliver meaningful innovation for people living with anxiety and other neuropsychiatric conditions.”

“I’m excited to join the Newleos Board at such a pivotal time,” said Dr. Brannan. “The team’s patient focus and commitment to scientific rigor is clear, and I believe their

innovative approach to targeting neuropsychiatric disorders has strong potential to address major unmet needs in the field."

In addition to Karuna, Dr. Brannan has held senior roles in clinical development and medical affairs, including Therapeutic Head of Neuroscience at Takeda, Vice President for Clinical Research and Medical Affairs at Forum Pharmaceuticals, and senior roles at Novartis, Cyberonics, and Eli Lilly. He has been active in the development of multiple important CNS treatments including Cymbalta, Exelon Patch, Trintellix, and VNS for treatment-resistant depression. Prior to joining the pharmaceutical industry, Dr. Brannan was a faculty member at the University of Texas Health Science Center at San Antonio (UTHSCSA), specializing in mood and anxiety patient care, running a clinical research unit, and conducting neuroimaging research. He trained in psychiatry at UTHSCSA and holds an M.D. from the University of Texas Health Science Center at Dallas. He has over 60 publications and routinely speaks at industry conferences.

"There remains a profound unmet need for safe, effective, and fast-acting treatments for generalized anxiety disorder, which continues to impact tens of millions of people worldwide," said Federico Bolognani, M.D., Ph.D., Co-founder and Chief Medical Officer of Newleos Therapeutics. "While current therapies often fall short due to limited efficacy or unacceptable side effects, NTX-1955 represents a fundamentally different approach. By selectively modulating GABAA-γ1 receptors, we aim to preserve the potent anxiolytic effects of GABAergic modulation while minimizing the sedation, cognitive impairment, and dependence risks seen with benzodiazepines. With the initiation of our Phase 1b studies in the EU, we are building upon the established safety and tolerability profile of NTX-1955 as we take an important step toward validating this novel mechanism in humans and advancing a new class of anxiolytics."

About Generalized Anxiety Disorder

Generalized anxiety disorder (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 GABAA-γ1 positive allosteric modulator (PAM), originally discovered by Roche and now in development for generalized anxiety disorder (GAD). GABAA is the major inhibitory neurotransmitter in the brain and positive allosteric modulation of the GABAA receptor is a well-validated approach for managing GAD symptoms. Nonselective GABAA PAMs such as benzodiazepines, while robust anxiolytics, modulate GABAA 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 GABAA-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 anxiety models 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 GABAA-γ1.

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 GABAA-γ1, V1a, TAAR1 and GABAA-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.

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