Neuphoria Therapeutics Completes Target Enrollment in Phase 3 AFFIRM-1 Trial of BNC-210 in Social Anxiety Disorder (SAD)

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Topline data anticipated in early Q4 2025

BURLINGTON, Mass., Sept. 04, 2025 (GLOBE NEWSWIRE) -- Neuphoria Therapeutics Inc. (Nasdaq: NEUP) ("Neuphoria" or the "Company"), a clinical-stage biotechnology company developing impactful treatments for neuropsychiatric disorders, today announced the achievement of target enrollment of 332 participants in the AFFIRM-1 Phase 3 trial evaluating lead candidate BNC-210 as a first-in-class, acute, "as needed", fast-acting treatment for social anxiety disorder (SAD).

"We are thrilled to reach our target enrollment in the AFFIRM-1 trial evaluating BNC-210 as a transformative therapeutic for the treatment of SAD," said Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Neuphoria. "Achieving this milestone puts us on a clear path toward our first Phase 3 data for BNC-210, now expected early in the fourth quarter."

About BNC-210

BNC-210 is an oral, proprietary, selective negative allosteric modulator of the α7 nicotinic acetylcholine receptor under development for the treatment of SAD and post-traumatic stress disorder (PTSD). BNC-210 has been given FDA Fast Track designation for acute treatment of SAD and other anxiety related disorders, and for treatment of PTSD and other trauma and stressor related disorders. BNC-210 has demonstrated rapid-onset, broad and meaningful anti-anxiety effects in completed clinical trials in SAD, generalized anxiety disorder (GAD) and panic attacks without evidence of sedation, impairments in cognition or addiction potential.

About AFFIRM-1

The AFFIRM-1 Phase 3 clinical trial is a multi-center, double-blind, two-arm, parallel group, placebo-controlled trial evaluating the safety and efficacy of a single, acute dose of 225 mg of BNC-210 versus placebo. Participants in the trial are randomized 1:1 to receive a single dose of 225 mg BNC-210 or matched placebo. Approximately one hour after dosing, participants are introduced to a public speaking challenge and have two minutes to prepare for the speech (anticipation phase) before delivering a five-minute speech in front of a small audience (performance phase). The primary endpoint of the trial is the change from baseline to the average of the performance phase of the public speaking challenge in Subjective Units of Distress Scale (SUDS) scores. Secondary endpoints include change in SUDS score from baseline to the average of the anticipation phase, changes in the Clinical Global Impression – Severity (CGI-S) scale, and self-assessment with the State Trait Anxiety Inventory (STAI-State) and the Patient Global Impression – Improvement (PGI-I) scale. A follow-up visit occurs one week after the public speaking challenge.

About Social Anxiety Disorder

SAD is a significant and persistent fear of social and performance-related situations. As one of the most common mental disorders in the United States, an estimated 31 million Americans will suffer from SAD at some point in their lives. SAD can interfere with a person's ability to work, make it difficult to maintain friendships, family relationships, and romantic partnerships, cause a person to avoid lifestyle activities like dining out and traveling, and make normal parts of everyday life such as grocery shopping, calling a handyman, or picking up coffee challenging.

About Neuphoria Therapeutics Inc.

Neuphoria is a clinical-stage biotechnology company dedicated to developing therapies that address the complex needs of individuals affected by neuropsychiatric disorders. Neuphoria is advancing its lead drug candidate, BNC-210, an oral, proprietary, selective negative allosteric modulator of the α7 nicotinic acetylcholine receptor, for the acute, "as needed" treatment of SAD and for chronic treatment PTSD. BNC-210 is a first-of-its-kind, well-tolerated, broad spectrum anti-anxiety experimental therapeutic, designed to restore neurotransmitter balance in relevant brain areas, providing rapid relief from stress and anxiety symptoms without the common pitfalls of sedation, cognitive impairment, or addiction. In addition, Neuphoria has a strategic partnership with Merck & Co., Inc. (known as MSD outside the United States and Canada) with two drugs in early-stage clinical trials for the treatment of cognitive deficits in Alzheimer's disease and other central nervous system conditions. Neuphoria's pipeline also includes the α7 nicotinic acetylcholine receptor next generation and the Kv3.1/3.2 preclinical programs, both in the lead optimization development stage.

Forward-Looking Statements

Neuphoria cautions that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "potential," "continue" or "project" or the negative of these terms or other comparable terminology

are intended to identify forward-looking statements. The forward-looking statements are based on our current beliefs, plans, burn rate and expectations. Certain forward-looking statements, including (without limitation) about (1) Neuphoria's ability to develop and expand its business, successfully complete development of its current product candidates, the timing of commencement and/or completion of various clinical trials and receipt of data and current and future collaborations for the development and commercialization of its product candidates, (2) the market for drugs to treat CNS diseases and pain conditions, (3) Neuphoria's financial resources, and (4) assumptions underlying any such statements. The inclusion of forward-looking statements should not be regarded as a representation by Neuphoria that any of its plans will be achieved. Future events and actual results could differ materially from those set out in, contemplated by or underlying the forward-looking statements due to a number of important factors. Certain forward-looking statements involve contracts, licenses and arrangements involving third parties and their respective clinical trial and research and development projects that are out of our control, including our agreements with Merck and Carina. They may terminate or delay any or all such projects in their discretion pursuant to the terms of our agreements with them, which could result in the Company not realizing any further milestone payments or further progress on the respective product pathways. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in the Company's business and other risks described in the Company's filings with the SEC, including the Company's Annual Report on Form 10-K, Quarterly Report on Form 10-Q, each filed with the SEC, and its other reports. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Neuphoria undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. Further information regarding these and other risks, uncertainties and other factors is included in Neuphoria's filings with the SEC, copies of which are available from the SEC's website (www.sec.gov) and on Neuphoria's website (www.neuphoriatx.com) under the heading "Investor Center." All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995. Neuphoria expressly disclaims all liability in respect to actions taken or not taken based on any or all the contents of this press release.

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