Bionomics Initiates AFFIRM-1, a Phase 3 Clinical Trial with BNC210 for Social Anxiety Disorder

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- ***Topline results are expected in Q3 2025***

ADELAIDE, Australia and CAMBRIDGE, Mass., July 18, 2024 (GLOBE NEWSWIRE) -- Bionomics Limited (Nasdaq: BNOX) (Bionomics or Company), a biotechnology company developing novel, potential first-in-class, allosteric ion channel modulators to treat patients suffering from serious central nervous system (CNS) disorders with high unmet medical need, today announced the initiation of patient screening for the Phase 3 AFFIRM-1 trial evaluating the safety and efficacy of BNC210 for the acute, as-needed treatment of social anxiety disorder (SAD).

"AFFIRM-1 trial initiation marks a major achievement for Bionomics as we enter the Phase 3 clinical stage, made possible by our recent capital raise and our expert clinical development team that has a proven track record of executing high quality trials on time and within budget.", said Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Bionomics. "The Phase 3 study expands on the findings of the Phase 2 PREVAIL trial and brings us closer to potentially transforming the treatment paradigm for the millions of individuals who lack safe and effective acute, as-needed treatment options to assist them in facing anxiety-inducing situations."

AFFIRM-1 targets enrollment of 330 adult patients with SAD at clinical sites in the United States (U.S.). It is a multi-center, double-blind, two-arm, parallel group, placebo-controlled trial. Participants will be randomized 1:1 to receive a single dose of 225 mg BNC210 or matched placebo about one hour before speaking in public. The primary endpoint will compare BNC210 to placebo using the Subjective Units of Distress Scale (SUDS) to measure self-reported anxiety levels during a public speaking task. Secondary efficacy endpoints include the Clinical and Patient Global Impression (CGI and PGI, respectively) scales and the State-Trait Anxiety Inventory (STAI).

BNC210 is an α7 nicotinic receptor small molecule with a unique and differentiating profile that is fast-acting, non-sedating, non-addictive and non-cognition impairing, and is suitable for both acute and chronic administration in neuropsychiatric disorders. The Phase 3 initiation of AFFIRM-1 follows results from the full data analysis of the Phase 2 PREVAIL study and the End-of-Phase 2 (EoPh2) meeting with the U.S. Food and Drug Administration (FDA) in Q3 2023 during which agreement was reached on the roadmap for a future NDA submission. Beyond SAD, BNC210 has demonstrated effects in reducing panic symptoms in pharmacologically induced panic attacks, in reducing anxiety levels in general anxiety disorder, and in reducing in total symptom severity in post-traumatic stress disorder (PTSD).

Dr Papapetropoulos added, "We remain committed to advancing BNC210, a potential first- and best-in-class candidate with FDA Fast Track designation for both SAD and PTSD and look forward to sharing an update about our PTSD program following the recently completed EoPh2 meeting with the FDA."

About AFFIRM-1

The AFFIRM-1 trial aims to enroll approximately 330 adult patients diagnosed with SAD and who rate ≥60 on the Liebowitz Social Anxiety Scale (LSAS). Study participants are randomized 1:1 to receive a single acute dose of either 225 mg BNC210 or a matched placebo. Approximately 1 hour after dosing, participants are introduced to the public speaking challenge and have 2 minutes to prepare for the speech (anticipation phase). Participants are then required to give a 5-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 subscale) and the Patient-Global Impression - Improvement (PGI-I) scale. A follow-up visit occurs 1 week after the public speaking challenge.

About Social Anxiety Disorder (SAD)

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 BNC210

Formulated as an oral solid tablet BNC210 is a negative allosteric modulator of the α7 nicotinic acetylcholine receptor under development for the treatment of social anxiety disorder (SAD) and post-traumatic stress disorder (PTSD). BNC210 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.

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About Bionomics Limited

Bionomics (NASDAQ: BNOX) is a clinical-stage biotechnology company developing novel, potential first-in-class, allosteric ion channel modulators to treat patients suffering from serious central nervous system (CNS) disorders with high unmet medical need. Bionomics is advancing its lead drug candidate, BNC210, an oral, proprietary, selective negative allosteric modulator of the α7 nicotinic acetylcholine receptor, for the acute treatment of social anxiety disorder (SAD) and chronic treatment of post-traumatic stress disorder (PTSD). Beyond BNC210, Bionomics 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 CNS conditions. Bionomics' pipeline also includes preclinical assets that target Kv3.1/3.2 and Nav1.7/1.8 ion channels being developed for CNS conditions of high unmet need.www.bionomics.com.au

Forward-Looking Statements

Bionomics 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 and expectations and include, but are not limited to: the closing of each tranche of the Company's private placement financing, the achievement of certain milestones for the various tranches, the timely funding to the Company by each investor in the private placement, the timing, size and expectation of the closing of the private placement; and expectations regarding market conditions, the satisfaction of customary closing conditions related to the private placement and the anticipated use of proceeds therefrom; and the Company's expectation that its current cash, cash equivalents, and marketable securities will fund our operations into the third quarter of 2025. The inclusion of forward-looking statements should not be regarded as a representation by Bionomics that any of its plans will be achieved. 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 Securities and Exchange Commission (SEC), including, but not limited to, the Company's Annual Report on Form 20-F 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 Bionomics 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 Bionomics' filings with the SEC, copies of which are available from the SEC's website (www.sec.gov) and on Bionomics' website (www.bionomics.com.au) 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. Bionomics expressly disclaims all liability in respect to actions taken or not taken based on any or all the contents of this press release.