Bionomics Reports Promising Full Results Analysis from PREVAIL Phase 2 Study of BNC210 Social Anxiety Disorder (SAD)

March 9, 2023

- ***Both doses of BNC210 as an acute treatment resulted in reductions in anxiety across multiple phases of the public speaking challenge***
- ***Results achieved statistical significance in post-hoc analysis of the full data set and in relevant subpopulations***
- ***Favourable safety, tolerability and PK findings are consistent with a fast-acting non-sedating anxiolytic profile***
- ***The company is planning an End of Phase 2 (EoPh2) meeting to discuss BNC210's late-stage SAD program 2H 2023***
- ***Webcast and conference call scheduled for Thursday, March 9, 2023 at 8:00 AM EST (Friday, March 10, 2023 at 12:00 AM AEDT)***

ADELAIDE, Australia, March 08, 2023 (GLOBE NEWSWIRE) -- Bionomics Limited (Nasdaq: BNOX | ASX: BNO) (Bionomics or Company), a clinical-stage biopharmaceutical company developing novel allosteric ion channel modulators for serious central nervous system (CNS) disorders with high unmet medical need, today announced the release of a comprehensive analysis of the data from its Phase 2 PREVAIL study to evaluate the efficacy and safety of BNC210, a novel α7 nicotinic acetylcholine receptor negative allosteric modulator, for the acute treatment of Social Anxiety Disorder (SAD). These data support late-stage development of BNC210 in SAD.

The PREVAIL study was designed with the aim of uncovering the best methodological approaches to measure the therapeutic potential of BNC210 in the acute treatment of SAD, a setting with no approved treatments, and evolving understanding of clinical trial methodologies. While PREVAIL did not meet its primary endpoint, the December 2022 topline data readout revealed encouraging trends in the prespecified endpoints that focused on individual phases of the public speaking task. These results supported a post-hoc in-depth analysis of the full dataset to better understand the true potential of the drug and guide late-stage trial design.

This full analysis revealed that BNC210's therapeutic potential was not limited to a single task phase but was present throughout the speaking task, including the performance phase of the public speaking challenge and the anticipatory period immediately prior. Moreover, administration of both 225 mg and 675 mg BNC210 doses resulted in therapeutic responses of similar magnitude, which allowed for the data from the two arms to be combined, enhancing the dataset's statistical power (BNC210 n = 101, placebo n = 50).

Participants that received BNC210 experienced significantly less anxiety during the public speaking task (combined resting, anticipation, and performance phases) compared to participants that received placebo as measured by the Subjective Units of Distress Scale (SUDS), the study's primary outcome measure ($p=0.037$). Similar results were observed when combining the two high-anxiety phases (anticipation and performance, $p=0.044$). These therapeutic effects are comparable to those reported with benzodiazepines supporting the clinical meaningfulness of BNC210's anxiolytic effects. Converging trends favouring BNC210 were also observed in the State-Trait Anxiety Inventory (STAI). Furthermore, subgroup analyses indicated that the younger participants (30 years and below) showed stronger responses to BNC210 with significant separation from placebo (anticipation and performance, $p=0.023$) on the SUDS. This younger cohort may be particularly relevant given that SAD often exhibits early onset, typically during adolescence or early adulthood.

In addition to the favourable efficacy, the overall safety profile of BNC210 was found to be consistent with a non-sedating anxiolytic. The new oral tablet formulation performed as predicted by earlier studies in healthy volunteers and exhibited a fast-acting pharmacokinetic profile that supports the use of BNC210 in the acute treatment of SAD. In sum, the complete analysis of the data indicates that patients who received BNC210 exhibited a statistically significant separation over those receiving placebo in well-powered post-hoc analyses across trial phases and identified a patient population in which the experimental therapeutic enhanced the probabilities of success and possesses a favourable safety and tolerability profile.

The company will share details on PREVAIL during a webcast as detailed below and plans to discuss results and the overall design of the registrational program with the FDA in the coming months.

"PREVAIL revealed BNC210's potential as a non-sedating anxiolytic for the acute treatment of SAD. These results follow positive findings in a panic attack model and in patients with generalized anxiety disorder, further support clinical proof of concept in anxiety disorders and de-risk BNC210's continuing development" remarked Spyros Papapetropoulos MD, PhD, President and Chief Executive Officer of Bionomics. "We look forward to meeting with FDA in the coming months to discuss our clinical path forward for this exciting new therapeutic candidate."

"The full analysis of the data indicates that patients receiving BNC210 show reduced distress compared to placebo. Given the observed effect size in PREVAIL, there is reason to believe that a subsequent trial with a larger sample size could achieve its primary endpoint," commented Dr. Murray Stein, MD, MPH. Dr. Stein continued "The finding that a statistically significant separation from the placebo occurred when the two dose levels and the anticipation and performance phases were combined is important. Both anticipation and performance are very relevant to understand clinically, so there would be a lot of value in combining these phases as a key data output in future trials."

About PREVAIL

The PREVAIL trial enrolled 151 adult patients at 15 sites with diagnosed SAD and who rated ≥ 70 on the Liebowitz Social Anxiety Scale. Study

participants were randomized 1:1:1 to receive a single dose of either a placebo or 225 mg or 675 mg BNC210. All participants completed the study. After dosing, there was a 55-minute rest period followed by the reading of the challenge instructions, a 2-minute anticipation-preparation period, a 5-minute speaking challenge and a 30-minute post-challenge period. The primary outcome measure was a self-assessment during the speaking challenge using the Subjective Units of Distress Scale (SUDS), a standard visual analog scale from 0-100 that measures self-reported intensity of anxiety and/or distress. SUDS is widely considered to be the most qualified outcome measure in social anxiety trials that utilize the public speaking task. Secondary outcome measures included self-assessment with SUDS during the preparation-anticipation phase, and self-assessment with the State-Trait Anxiety Inventory (STAI, State subscale), a self-reported questionnaire with 20 anxiety-related questions marked on a 4-point scale. Both primary and secondary endpoints were selected in the absence of prior guiding data from BNC210 in SAD.

About Social Anxiety Disorder

SAD is a significant and persistent fear of social and performance-related situations. 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 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.

Conference Call Information

Bionomics will host a webcast and conference call on Thursday, March 9, 2023 at 8:00 AM EST (Friday, March 10, 2023 at 12:00 AM AEDT) to discuss how the PREVAIL study achieved its goals, constituted a proof of concept in SAD, and provided valuable information for designing the late-stage BNC210 program. A live question and answer session will follow the formal presentations. To access a recording of this event, please visit "News & Events" in the "Investors" section of the Bionomics website at bionomics.com.au. An archived replay will be available for approximately 90 days following the presentation.

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About Bionomics Limited

Bionomics (ASX:BNO, NASDAQ:BNOX) is a clinical-stage biopharmaceutical company developing novel, allosteric ion channel modulators designed to transform the lives of patients suffering from serious 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 central nervous system conditions.

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. These statements include the Company's plans to advance the development of its product candidates, the timing of achieving any development or regulatory milestones, and the comparability and potential of such product candidates, including to achieve any benefit or profile or any product approval or be effective. 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 the Company's Annual Report on Form 20-F filed with the SEC on October 14, 2022, 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 is included in Bionomics' filings with the SEC 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.