



Bionomics Publishes the Positive Results from the Phase 2 ATTUNE Study of BNC210 in Patients with Post-Traumatic Stress Disorder in NEJM Evidence

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- BNC210 improved PTSD symptom severity at Week 12 with efficacy observed as early as Week 4
- Company plans to initiate a Phase 3 study of BNC210 in PTSD in H2 2025

ADELAIDE, Australia, and CAMBRIDGE, Mass., Dec. 09, 2024 (GLOBE NEWSWIRE) -- Bionomics Limited (Nasdaq: BNOX) (Bionomics or Company), a clinical-stage biotechnology company developing novel, 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 that the positive results from its Phase 2 ATTUNE study have been published in the [NEJM Evidence](#). The data were also presented yesterday at the 63rd Annual Meeting of the American College of Neuropsychopharmacology (ACNP) as part of the inaugural "Promising Targets" session.

"We are excited to publish the results of the ATTUNE in *NEJM Evidence*, a prestigious journal for innovative original research. This peer-reviewed publication further validates these significant results and underscores the differentiated clinical profile of BNC210, a potential best- and first-in class treatment for PTSD that is non-psychedelic, non-sedating and non-habit-forming," said Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Bionomics. "Since our successful End-of-Phase 2 meeting with the FDA earlier this year, we have been diligently preparing for the Phase 3 study of BNC210 in PTSD which we anticipate initiating in the second half of 2025, if not sooner."

Key results from the publication include:

- Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) total score improvement was observed with BNC210 compared with placebo ($p=0.048$) at Week 12 with improvement seen as early as Week 4
- Clinically meaningful and statistically significant improvements were also observed with BNC210 vs placebo in:
 - Depressive symptoms measured on the Montgomery-Åsberg Depression Rating Scale
 - Sleep measured on the Insomnia Severity Index
- Treatment-emergent adverse events (AEs) occurred in 70 (66.7%) patients in the BNC210 group and 56 (53.8%) in the placebo group. The most common AEs were headache, nausea, fatigue, and hepatic enzyme elevations.

"This publication highlights the encouraging and clinically meaningful improvements seen with BNC210 across several key PTSD symptoms," commented Murray B Stein, M.D., M.P.H.; Distinguished Professor of Psychiatry and Public Health at the University of California San Diego and a senior author of the paper. "Fewer than 50% of patients experience benefit with currently approved treatments and therefore there is a pressing need for new, well-tolerated, efficacious treatments. The ATTUNE data, along with the additional clinical data of BNC210 to date, positions it as a promising potential treatment and I look forward to further seeing it assessed in a larger Phase 3 trial."

The Company is planning to initiate the Phase 3 trial in PTSD in the second half of 2025. BNC210 is also being evaluated in a Phase 3 AFIRM-1 study in social anxiety disorder (SAD) with anticipated readout in Q3 2025.

FOR FURTHER INFORMATION PLEASE CONTACT:

General

Rajeev Chandra
Company Secretary
CoSec@bionomics.com.au

Investor Relations

Kevin Gardner
kgardner@lifesciadvisors.com

Investor Relations

Chris Calabrese
ccalabrese@lifesciadvisors.com

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 $\alpha 7$ 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](http://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.



Source: Bionomics Ltd