



Bionomics Initiates Phase 2 PREVAIL Study of BNC210 for the Acute Treatment of Social Anxiety Disorder

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EASTWOOD, Australia, Jan. 3, 2022 /PRNewswire/ -- Bionomics Limited (ASX: BNO,NASDAQ: [BNOX](#)) (**Bionomics or Company**), a clinical-stage biopharmaceutical company, is pleased to announce that it has initiated its Phase 2 clinical trial (the PREVAIL Study) to evaluate BNC210 for the acute treatment of Social Anxiety Disorder (SAD), with topline results expected by the end of 2022.

BNC210 is an oral, proprietary, selective negative allosteric modulator of the $\alpha 7$ nicotinic acetylcholine receptor in development for the acute treatment of SAD and chronic treatment of Post-Traumatic Stress Disorder (PTSD), with U.S. Food and Drug Administration (FDA) Fast Track designation for both clinical indications.

The PREVAIL Study SAD protocol was cleared by the FDA in November 2021, and it was granted ethics approval by a central U.S. Institutional Review Board (IRB) in December 2021. With these approvals in place, as well as site-level approvals, clinical sites in the U.S. are now activated and open to screening for potential study participants aged 18 to 65 years old with marked to severe SAD. Study participants will need to have a score of at least 70 on the Liebowitz Social Anxiety Scale, which is a scale that assesses a patient's reported level of social phobia in a range of social and performance situations. It is anticipated that 15 to 20 clinical sites in the U.S. will be involved in recruiting patients for this study.

In this randomised, double-blind, placebo-controlled trial, BNC210 will be evaluated as an acute, or single-dose, treatment for patients with SAD. Study participants will be randomly assigned to one of three treatment groups, 225 mg BNC210, 675 mg BNC210 or placebo, with approximately 50 participants in each group. They will be orally administered a single dose of their assigned treatment approximately one hour prior to taking part in an anxiety-provoking behavioral task involving a speaking challenge. The primary objective of the study is to compare each dose level of BNC210 to placebo on self-reported anxiety levels using the Subjective Units of Distress Scale (SUDS). Secondary objectives include two other scales measuring participants' anxiety levels (State-Trait Anxiety Inventory and Self-Statements During Public Speaking), as well as an evaluation of the safety and tolerability of BNC210 in this population.

"Anxiety disorders are a significant burden for our communities and approximately 18 million adults suffer from Social Anxiety Disorder in the United States alone. Patients will typically experience persistent and intense fear of social or performance-related situations when exposed to unfamiliar people or to possible scrutiny by others. They will often engage in avoidance behaviours to manage their fears, which can interfere with functioning, increase loneliness and social isolation, and diminish quality of life. There is a great unmet need for fast-acting, as-needed treatments for these patients because the only FDA approved medications for Social Anxiety Disorder take several weeks or longer before they impact symptoms. Safe and effective on-demand treatments could help people with Social Anxiety Disorder engage with, rather than avoid, anxiety-provoking situations when they need to the most," said Bionomics' consultants at University of California (San Diego) Drs. Charles Taylor (Associate Professor, Department of Psychiatry) and Murray Stein (Distinguished Professor, Department of Psychiatry).

"The new tablet formulation of BNC210, which is rapidly absorbed and reaches maximal concentrations in the blood in approximately one hour, is being evaluated in the PREVAIL study as an oral as-needed treatment for SAD patients to better cope with anticipated anxiety-provoking social interactions and other public settings. We look forward to taking advantage of the Fast Track designations for both SAD and PTSD treatment indications, and our goal is to report topline data in late 2022 for the PREVAIL Study and by the middle of 2023 for the ongoing Phase 2b PTSD ATTUNE Study," said Bionomics' Executive Chairman, Dr. Errol De Souza.

Released on authority of the Executive Chairman.

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 central nervous system ("CNS") disorders with high unmet medical need. Bionomics is advancing its lead product 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 central nervous system conditions.

www.bionomics.com.au

Factors Affecting Future Performance

This announcement contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this announcement that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' drug candidates (including BNC210), drug discovery programs, ongoing and future clinical trials, and timing of the receipt of clinical data for our drug candidates are deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by these forward-looking statements, including unexpected safety or efficacy data, unexpected side effects observed in clinical trials, risks related to our available funds or existing funding arrangements, our failure to introduce new drug candidates or obtain regulatory approvals in a timely manner or at all, regulatory changes, inability to protect our intellectual property, risks related to our international operations, as well as other factors. Results of studies performed on our drug candidates and competitors'

drugs and drug candidates may vary from those reported when tested in different settings.

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