Bionomics Limited

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ASX ANNOUNCEMENT
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Bionomics Receives FDA Clearance of IND for Evaluation of BNC210 in a Phase 2 Social Anxiety Disorder PREVAIL Study

- **U.S. FDA clearance of IND for BNC210 evaluation as an acute treatment for patients with Social Anxiety Disorder in a Phase 2 clinical trial, the PREVAIL Study**
- **The PREVAIL Study remains on target to initiate by end of 2021 and is expected to read out topline data by end of 2022**

Bionomics Limited (ASX:BNO, OTCQB:BNOEF) (**Bionomics** or **Company**), a clinical-stage biopharmaceutical company, is pleased to announce that it has received U.S. Food and Drug Administration (FDA) clearance to proceed with evaluating its lead clinical compound, BNC210, for the acute treatment of Social Anxiety Disorder (SAD) in a Phase 2 clinical trial named the PREVAIL Study.

BNC210 is an oral proprietary selective negative allosteric modulator of the α7 nicotinic acetylcholine receptor in development for the acute treatment of SAD and chronic treatment of Post-Traumatic Stress Disorder (PTSD). Following encouraging results in a previous Phase 2a study in Generalised Anxiety Disorder (GAD) patients where a single oral dose administration of BNC210 showed significantly reduced connectivity between the amygdala and the anterior cingulate cortex, a network involved in regulating anxious responses to aversive stimuli, BNC210 will now be evaluated as an acute, or single-dose, treatment for patients with SAD.

The PREVAIL Study is a randomised, double-blind, multi-centre Phase 2 clinical trial which will compare BNC210 to placebo on anxiety levels in patients with SAD during an anxiety-provoking behavioural task such as being asked to speak on a topic. Participants will be orally administered a single dose of study treatment approximately one hour prior to the behavioural task. The proprietary tablet formulation of BNC210 being used in this study is rapidly absorbed and levels in the circulation are expected to be around their peak concentrations at the time of the behavioural task. The primary objective of the study is to compare BNC210 to placebo on self-reported anxiety levels using the Subjective Units of Distress Scale (SUDS) during the behavioural task. Secondary objectives include other scales measuring participants' anxiety levels, in anticipation of, and during the behavioural task, as well as an evaluation of the safety and tolerability of BNC210 in this population.

Premier Research, a global Contract Research Organisation (CRO) headquartered in the United States, is contracted to manage the PREVAIL Study, which will be conducted according to Good Clinical Practice (GCP) guidelines. The study will be conducted at approximately 15 sites in the United States and is expected to recruit approximately 150 adult patients suffering with SAD. The study participants must score at least 70 on the Liebowitz Social Anxiety Scale (i.e., marked to severe social anxiety), which is a scale that assesses a patient's reported level of social phobia in a range of social interactions and performance situations during the past week.

BNC210 and placebo supplies for the study have been manufactured under current Good Manufacturing Practice (cGMP) standards and are packaged ready for the trial. We are targeting commencement of the trial by the end of this year and expect to report topline data by the end of 2022.

"Anxiety disorders are a significant burden for our communities and approximately 18 million adults suffer from Social Anxiety Disorder in the United States alone. There is no FDA-approved, fast-acting, as-needed treatment for SAD and the current standard of care, FDA-approved antidepressants and off-label use of benzodiazepines, have significant potential side effects and safety concerns. The new oral tablet formulation of BNC210, which is rapidly absorbed and is expected to reach maximal concentrations in the blood in approximately 45 to 105 minutes is being evaluated for the acute treatment of SAD patients to better cope with anticipated anxiety-provoking social interactions and other public settings. We look forward to launching the SAD trial while continuing recruitment in our ongoing Phase 2b ATTUNE study for BNC210 for the treatment of Post-Traumatic Stress Disorder with the goal of reporting topline data from these trials in late 2022 and the first half of 2023, respectively," said Bionomics' Executive Chairman, Dr. Errol De Souza.

Released on authority of the Executive Chairman.

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About Bionomics Limited

Bionomics (ASX:BNO, OTCQB:BNOEF) 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 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.

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), its licensing agreements with Merck & Co. and any milestone or royalty payments thereunder, drug discovery programs, ongoing and future clinical trials, and timing of the initiation of clinical trials and receipt and disclosure 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 arrangements, delays or difficulties associated with conducting clinical trials, our failure to introduce new drug candidates or platform technologies 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.