Bionomics Limited

ABN 53 075 582 740

ASX ANNOUNCEMENT
20 SEPTEMBER 2021

Bionomics Prepares BNC210 for Start of Phase 2 Acute Treatment of Social Anxiety Disorder Trial

- **Rapid oral absorption of BNC210 novel tablet formulation potentially well-suited for acute treatment of anxiety in patients with Social Anxiety Disorder**
- **Phase 2 clinical trial on target to start by end of 2021 and 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 as part of its broader pipeline expansion strategy and based on anti-anxiety signals in Generalised Anxiety Disorder (GAD) patients, it has decided to proceed with evaluating its lead clinical compound, BNC210, for acute treatment of Social Anxiety Disorder (SAD) with a planned commencement of a clinical trial by the end of this year.

BNC210 is an oral proprietary selective negative allosteric modulator of the α7 nicotinic acetylcholine receptor in development for the treatment of anxiety and trauma- and stressor-related disorders. A previous in-clinic Phase 2a study in GAD patients demonstrated that single dose administration of the liquid suspension formulation of BNC210 showed significant anti-anxiety signals as measured in brain imaging and behavioural studies, but without evidence of sedation or addictive potential. However, the slow absorption of the liquid suspension formulation of BNC210 and the requirement for it to be taken with food for optimal absorption, would limit its use in “real world” situations for the acute treatment of anxiety. A new solid dose tablet formulation of BNC210 has been developed showing much improved and rapid absorption and we plan to use the tablet formulation for the Phase 2 acute treatment clinical trial in SAD patients.

The Phase 2 SAD trial protocol has been developed with input from Bionomics’ Clinical Advisory Board members and will compare BNC210 to placebo on anxiety levels using the Subjective Units of Distress Scale (SUDS) during an anxiety-provoking behavioural task following a single dose treatment with the study drug. Drug product has already been manufactured and study start-up activities are underway. It is anticipated that approximately 15 sites in the U.S. will be involved in the trial, recruiting approximately 150 patients suffering with SAD. We intend to submit an Investigational New Drug (IND) application to the U.S. FDA in time for the commencement of the study by the end of this year, if the IND goes into effect with the FDA.

"Anxiety disorders are a significant burden for our communities and approximately 18 million American adults suffer from Social Anxiety Disorder in the U.S. alone. There is no FDA-approved, fast-acting, as-needed treatment for SAD and 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 reaches maximal concentrations in the blood in approximately 45 to 105 minutes may be well-suited 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 BNC210 Phase 2b Post-Traumatic Stress Disorder ATTUNE study with the goal of reporting topline data from the trials in late 2022 and the first half of 2023, respectively." said Bionomics' Executive Chairman, Dr. Errol De Souza.

Released on authority of the Board.

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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.

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), 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.