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ASX ANNOUNCEMENT
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U.S. FDA Grants Bionomics Fast Track Designation to BNC210 for the Acute Treatment of Social Anxiety Disorder and Other Anxiety Related Disorders

Bionomics Limited (ASX:BNO, OTCQB:BNOEF) (**Bionomics** or **Company**), a clinical-stage biopharmaceutical company, is pleased to announce that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the BNC210 development program for the acute treatment of Social Anxiety Disorder (SAD) and other anxiety-related disorders. In November 2019, the FDA granted Fast Track designation to the BNC210 development program for the treatment of Post-Traumatic Stress Disorder (PTSD) and other trauma-related and stressor-related disorders.

Fast Track designation is a FDA program intended to facilitate and expedite development and review of new drugs that demonstrate the potential to address unmet medical need in the treatment of a serious or life-threatening disease or condition. A drug that receives Fast Track designation is eligible for some, or all, of the following:

- more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- more frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers;
- eligibility for priority review and accelerated approval, if relevant criteria are met; and
- possible review of the New Drug Application (NDA) on a rolling basis. NDA review usually does not begin until a company has submitted the entire drug application to the FDA. When an NDA is eligible for rolling review, FDA begins reviewing completed sections of an NDA before the entire NDA is submitted.

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 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 threat-avoidance behaviour and significantly reduced connectivity between the amygdala and the anterior cingulate cortex, a network involved in regulating anxious responses to aversive stimuli, BNC210 will be evaluated as an acute, or single-dose, treatment for patients with SAD in a planned Phase 2 clinical trial named the PREVAIL Study that we expect to initiate by the end of 2021.

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 drug 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.

"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 reaches close to maximal concentrations in the blood in approximately one hour, 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 taking advantage of the Fast Track designations for both the SAD and PTSD treatment indications and launching the SAD Phase 2 PREVAIL trial before the end of 2021, with the goal of reporting topline data in late 2022, while continuing recruitment in our ongoing Phase 2 PTSD ATTUNE Study." 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.

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.