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ASX ANNOUNCEMENT

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Bionomics Initiates Phase 2b ATTUNE Study of BNC210 in PTSD

Bionomics Limited (ASX: BNO, OTCQB:BNOEF) (**Bionomics** or **Company**), a global, clinical stage biopharmaceutical company, is pleased to announce that it has initiated a Phase 2b trial (the ATTUNE Study) to evaluate the tablet formulation of BNC210 in patients with Post-Traumatic Stress Disorder (PTSD) with top line results expected in 1H 2023.

BNC210 is a novel, first-in-class, negative allosteric modulator of the $\alpha 7$ nicotinic acetylcholine receptor in development for the treatment of anxiety and stressor-related disorders and has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of PTSD and other trauma- and stressor-related disorders, recognising the high unmet medical need in the treatment of such serious conditions.

The ATTUNE Study is a randomised, double-blind, placebo-controlled, multi-centre Phase 2b clinical trial with a 12-week treatment period. The primary objective is to compare BNC210 to placebo on the improvement in PTSD symptom severity as measured by the Clinician Administered PTSD scale for DSM-5 (CAPS-5) following 12 weeks of treatment. In addition to the clinician evaluation of PTSD symptom severity, there are a number of secondary objectives to measure patient-reported symptoms of PTSD, changes in anxiety and depression symptoms, and global and social functioning in the study participants. An oral tablet formulation of BNC210, showing much improved absorption over the previous liquid suspension formulation, will be evaluated in this study. The dose of BNC210 (900 mg twice daily) was selected based on achieving exposure levels that are predicted from a pharmacometric blood exposure-CAPS-5 response model, built on a previous BNC210 trial data set (RESTORE), as necessary to meet the primary endpoints for effectiveness for treating PTSD patients in clinical trials.

Premier Research, Global Contract Research Organisation (CRO) headquartered in the U.S., is contracted to manage the ATTUNE Study which will be conducted at around 25 clinical sites in the U.S., recruiting approximately 200 patients with PTSD. Premier Research is recognised as a leading CRO supporting industry-sponsored PTSD studies. Dr. Frank Weathers, author of the CAPS-5, is delivering a comprehensive training program to clinical site raters in the use of the CAPS-5 assessment scale ensuring collection of robust and reliable study data for the primary endpoint measure.

The trial protocol was submitted to the U.S. FDA at the end of May 2021 and on 22 June 2021 was granted ethics approval by a central human ethics Institutional Review Board (IRB). Clinical sites are activated and open to screen for potential study participants.

"PTSD affects up to 8% of adults in their lifetime and is a significant burden for patients suffering from the disorder with no newly approved pharmacotherapy in almost two decades beyond the two antidepressants sertraline and paroxetine. Data from our recent 7-day pharmacokinetic study in

healthy volunteers demonstrated the new spray dry oral solid dose tablet formulation of BNC210 at the dosing regimen being used in the ATTUNE PTSD trial is well-tolerated and not only meets but exceeds the blood exposure predicted from the pharmacometric analysis as necessary for future trials. Beyond PTSD, we will be leveraging the rapid absorption profile of the tablet formulation for an acute treatment in Social Anxiety Disorder patients and look forward to providing details of the study design and timelines in the near future" said Bionomics' Executive Chairman, Dr Errol De Souza.

Released on authority of the Board.

FOR FURTHER INFORMATION PLEASE CONTACT:

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About Bionomics Limited

Bionomics (ASX: BNO, OTCQB: BNOEF) is a clinical-stage biopharmaceutical company leveraging its proprietary platform technologies to discover and develop a deep pipeline of best-in-class, novel drug candidates for patients affected by central nervous system (CNS) disorders. Bionomics' lead drug candidate BNC210 is a negative allosteric modulator of the $\alpha 7$ nicotinic acetylcholine receptor. BNC210 oral tablet formulation is currently being evaluated in a second Phase 2b trial for the treatment of Post-Traumatic Stress Disorder (PTSD) for which it was granted Fast Track designation by the FDA. BNC210 is also being evaluated as an acute treatment in Social Anxiety Disorder (SAD) patients and is expected to enter a Phase 2 trial. In addition, Bionomics has entered into a Memorandum of Understanding with EmpathBio Inc, a wholly owned subsidiary of Germany-based CNS clinical development company, atai Life Sciences, to collectively explore a combination drug treatment regimen with Bionomics' BNC210 and EmpathBio's 3,4- Methylenedioxymethamphetamine (MDMA) derivative EMP-01 for the treatment of 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.

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 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 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, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantage, 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.