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ASX ANNOUNCEMENT

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Bionomics Expanding BNC210 for Acute Treatment of Social Anxiety Disorder in Addition to Phase 2b Trial for Post-Traumatic Stress Disorder

- **Rapid oral absorption of BNC210 novel tablet formulation ideally suited for acute treatment of anxiety in patients with Social Anxiety Disorder**
- **BNC210 Phase 2b PTSD trial on target for start in mid-2021 with U.S. CRO Premier Research selected and clinical site identification underway**
- **Pipeline expansion puts Company on path for two Phase 2 programs underway in 2021**

Bionomics Limited (ASX: BNO, OTCQB:BNOEF) (**Bionomics** or **Company**), a global, clinical stage biopharmaceutical company, is pleased to announce that as part of its broader pipeline expansion strategy and based on anti-anxiety efficacy 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) while progressing toward the start of its planned Phase 2b trial in Post-Traumatic Stress Disorder (PTSD) in the middle of this year.

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 in November 2019 was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of PTSD. In addition to PTSD, a previous successful Phase 2a study in GAD patients demonstrated that acute administration of the liquid suspension formulation of BNC210 had significant anti-anxiety effects as measured in brain imaging and behavioural studies similar to benzodiazepines such as lorazepam but without evidence for sedation or addictive potential. The slow absorption of the liquid suspension formulation of BNC210 and the requirement for it to be taken with food for optimal absorption limited its use for the acute treatment of anxiety in patients with SAD. A new solid dose tablet formulation of BNC210 has been successfully developed, showing much improved and rapid absorption over the previous liquid suspension formulation, and will be used for the Phase 2 efficacy clinical trials in SAD and PTSD.

"Anxiety disorders are a significant burden for our communities and approximately 17 million American adults suffer from Social Anxiety Disorder. The new spray dry oral solid dose tablet formulation of BNC210 which is rapidly absorbed and reaches maximal concentrations in the blood in approximately one hour may be ideal for the acute treatment of SAD patients to better cope with anticipated anxiety-provoking social interactions and other public settings. We look forward to providing details on the Phase 2 SAD clinical trial design and timelines over the next quarter while we remain on track for initiation of our Phase 2b PTSD trial in mid-2021" said Bionomics' Executive Chairman, Dr Errol De Souza.

The Phase 2b PTSD trial protocol has been developed with input from Bionomics' Clinical Advisory Board members and will compare BNC210 (900 mg twice daily) 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. The dose of BNC210 has been selected based on achieving exposure levels that are predicted from a pharmacometric 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. Manufacturing of the drug supply for the trial is progressing well, and tablets for both BNC210 and placebo will soon be undergoing final testing, packaging, and labelling.

Premier Research, a U.S.-headquartered Contract Research Organisation (CRO), has been selected to manage the Phase 2b PTSD trial. Premier Research is recognised as a leading CRO supporting industry-sponsored PTSD studies and has conducted ~10 studies in this indication since 2014, including Bionomics' RESTORE trial. "In recent years, we've accumulated substantial experience conducting PTSD studies, which has made our experts particularly adept at delivering high quality clinical trials in this area. Collaborating again with Bionomics is the ideal way to leverage our collective experience in this space," said Krista Armstrong, PhD, Premier Research SVP, Clinical Development Services & Global Head of Neuroscience. "Our close relationships with key investigators in the field, including our important partnership with Dr. Frank Weathers, allows us to provide the fit-for-purpose and comprehensive rater training, and delivery execution necessary for conclusive results."

Premier Research will work in partnership with Dr. Weathers, author of the CAPS-5, to deliver the training program to clinical site raters in the use of the CAPS-5 assessment in Bionomics' Phase 2b clinical trial, ensuring collection of robust and reliable study data for the primary endpoint measure. Study start-up activities are underway including clinical site identification and selection. It is anticipated that around 25 sites in the U.S. will be involved in the trial, recruiting approximately 200 PTSD patients. The trial protocol will soon be submitted to the U.S. FDA and a central human ethics Institutional Review Board (IRB), in time for the commencement of the study in the middle of this year.

Released on authority of the Board.

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About Bionomics Limited

Bionomics (ASX: BNO, OTCQB: BNOEF) is a global, clinical stage biopharmaceutical company leveraging its proprietary platform technologies to discover and develop a deep pipeline of best in class, novel drug candidates. Bionomics' lead drug candidate BNC210, currently in development for initiation of a second Phase 2 trial for the treatment of PTSD, is a novel, proprietary negative allosteric modulator of the alpha-7 nicotinic acetylcholine receptor. 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.