

ASX ANNOUNCEMENT 9 July 2018

# END-OF-TREATMENT MILESTONE MET IN THE PHASE 2 CLINICAL TRIAL OF BNC210 FOR THE TREATMENT OF PTSD

Topline Data Anticipated to be Reported Late Third Quarter 2018

Bionomics Limited (ASX:BNO, OTCQX:BNOEF), a global, clinical stage biopharmaceutical company, today announces that all 193 patients enrolled in the RESTORE trial, a Phase 2 clinical trial designed to evaluate the safety and efficacy of its' therapeutic candidate BNC210 for the treatment of Post-Traumatic Stress Disorder (PTSD), have completed their treatment phase of the study. BNC210 is a novel, first-in-class, negative allosteric modulator of the alpha 7 nicotinic acetylcholine receptor.

The RESTORE trial is a randomised, double-blind, placebo-controlled Phase 2 clinical trial enrolling adult patients diagnosed with PTSD at 25 sites across the United States and Australia. The primary endpoint of this study is a decrease in PTSD symptoms as measured by the Clinician-Administered PTSD Scale (CAPS-5). Secondary endpoints include a decrease in symptoms of anxiety as measured by the Hamilton Anxiety Rating Scale (HAM-A) and symptoms of depression as measured by the Montgomery and Asberg Depression Rating Scale (MADRS).

The recruitment and treatment phases of this comprehensive international Phase 2 clinical trial were completed on time, confirming the ability of Bionomics to efficiently undertake large, multi-centre clinical trials in the neuroscience area. Bionomics hosted two Key Opinion Leader events focused on the potential of BNC210 to treat PTSD, in New York on April 13, 2018 and in London on April 17, 2018. A playback of the New York presentation can be found on the home page of Bionomics' website <a href="https://www.bionomics.com.au">www.bionomics.com.au</a>.

"BNC210 has the potential to be an innovative treatment for patients with PTSD with a solid foundation of clinical data supportive of development not only in PTSD but also in anxiety disorders and conditions where there is co-morbid anxiety and depression," said Dr Deborah Rathjen CEO & Managing Director of Bionomics.

Dr Rathjen thanked all those who participated in the trial "We are grateful to the patients and the medical community who participated in this trial."

In addition to this PTSD clinical trial, a Phase 2 clinical trial of BNC210 is currently recruiting elderly patients with agitation in the hospital setting. Agitated behavioural disturbance in elderly patients is a major clinical problem, occurring acutely in hospitalised patients and chronically in nursing home residents. These agitated behaviours can cause distress for the patient, distress to other patients, and can interfere with the therapeutic procedures for which the patient was hospitalised. Whilst there are no approved treatments for agitation in this elderly population, current options include

benzodiazepines and antipsychotics which can have severe adverse effects in elderly patients including sedation, stroke and sudden death, and hence their use is heavily restricted. The trial, designed for short treatment and rapid recruitment, will evaluate the effect of BNC210 on the resolution of agitation in hospitalised elderly patients and assess the safety and tolerability of BNC210 in this patient population. It will recruit approximately 40 elderly patients in specialist geriatric hospital wards across Australia, and is a randomised, double-blind, placebo-controlled design with a 5-day treatment period. Results of this clinical trial are anticipated to be available in Q1, CY2019.

#### FOR FURTHER INFORMATION PLEASE CONTACT:

Australia

Monsoon Communications Rudi Michelson +613 9620 3333 rudim@monsoon.com.au US

Stern Investor Relations Lilian Stern +1 212 362 1200 Lilian@sternir.com

### **About Bionomics Limited**

Bionomics (ASX: BNO) 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 Phase 2 for the treatment of agitation and for post-traumatic stress disorder, is a novel, proprietary negative allosteric modulator of the alpha-7 ( $\alpha$ 7) nicotinic acetylcholine receptor. Beyond BNC210, Bionomics has a strategic partnership with Merck & Co., Inc (known as MSD outside the United States and Canada).

## www.bionomics.com.au

#### About BNC210

BNC210 is a novel small molecule, orally-administered drug candidate being developed for anxiety and traumaand stressor-related disorders, that we believe has similar efficacy but improved tolerability compared to currently available drugs such as benzodiazepines, selective serotonin reuptake inhibitors, or SSRIs, and serotonin-norepinephrine reuptake inhibitors, or SNRIs. BNC210 is a first-in-class highly-selective negative allosteric modulator of the alpha-7 nicotinic acetylcholine ( $\alpha$ -7) receptor. The alpha-7 nicotinic receptor is highly expressed in the amygdala, which forms part of the emotional centre of the brain and recent data increasingly implicate acetylcholine and the alpha-7 receptor in the symptoms of anxiety and depression. To date, BNC210 has been evaluated in seven completed clinical trials in over 200 subjects. Additionally, 193 patients have been enrolled in a Phase 2 PTSD trial, and a Phase 2 trial for hospitalised elderly patients with agitation is open to recruitment.

# 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, BNC101 and BNC105), 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.