



ABN 53 075 582 740

ASX ANNOUNCEMENT
23 May 2018

COMMENCEMENT OF BNC210 PHASE 2 CLINICAL TRIAL FOR THE TREATMENT OF AGITATION

- **Treatment of agitation in the elderly in hospital and nursing home settings represents a rapid potential path to market for BNC210**
- **No currently approved treatments and significant unmet medical need**
- **Trial designed for rapid recruitment with results anticipated first quarter calendar year 2019; first patient recruited**
- **PTSD clinical trial on track; data anticipated second half calendar year 2018**

Bionomics Limited (ASX:BNO, OTCQX:BNOEF), a global, clinical stage biopharmaceutical company, today announces that a Phase 2 clinical trial of its therapeutic candidate, BNC210, has commenced in elderly patients with agitation in the hospital setting. The first participant has been recruited into the trial.

Agitated behavioural disturbance in elderly patients is a major unmet 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, 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 will be available in Q1, CY2019.

Dr Deborah Rathjen CEO & Managing Director commented “Bionomics has entered an important period with the results of two ongoing Phase 2 trials now anticipated near term. Agitation in the elderly, which has an underlying component of anxiety, has significant unmet treatment needs, with only approximately 9% of patients suffering agitation receiving drug treatment¹”.

“The hospitalised or nursing home agitation setting represents a rapid potential path to market for BNC210 and builds on the findings of the successful Phase 2 clinical trial of BNC210 in patients with Generalised Anxiety Disorder (GAD)”

“Last month we completed recruitment into our BNC210 Phase 2 clinical trial in patients suffering Post-Traumatic Stress Disorder (PTSD). As previously advised we anticipate data in 2H, CY2018,” Dr Rathjen added.

BNC210 is a novel, first-in-class, negative allosteric modulator of the alpha-7 nicotinic acetylcholine receptor. It has been shown to be well tolerated and not sedating. Furthermore, clinical trials have shown effects of BNC210 that are consistent with anti-anxiety action, even after a single administration, indicating a rapid onset of action and potential for therapeutic benefit in agitated elderly patients. Agitation in elderly patients has an underlying component of anxiety.

¹ National Institutes for Mental Health, Cowen Therapeutic Categories Outlook March 2016

FOR FURTHER INFORMATION PLEASE CONTACT:

Australia

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

US

Stern Investor Relations
Beth DeGiaccio
+1 212 362 1200
beth@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 generalised anxiety disorder and for post-traumatic stress disorder, is a novel, proprietary negative allosteric modulator of the alpha-7 ($\alpha 7$) nicotinic acetylcholine receptor. 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 trauma- and 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. Acetylcholine and the alpha-7 receptor are increasingly being implicated in the symptoms of anxiety and depression. Furthermore, the alpha-7 receptor is highly expressed in the amygdala, which forms part of the emotional centre of the brain. To date, BNC210 has been evaluated in seven completed clinical trials in over 200 subjects. Recruitment has just been completed in a Phase 2 Post-Traumatic Stress Disorder trial with 193 participants.

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.

Clinical Appendix

<p>Study Title: A Phase II Randomised, Double-blind, Placebo-controlled Pilot Study to Assess the Efficacy and Safety of BNC210 in Hospitalised Elderly Patients with Agitation</p>
<p>Study Number: BNC210.008</p>
<p>Clinical Phase: Phase 2</p>
<p>Study Design: Randomised, double-blind, parallel-dosing of BNC210 and placebo in a 1:1 ratio 5 days of treatment, with a 2 day follow up period Approximately 40 hospitalised elderly patients with agitation in specialist geriatric hospital wards across Australia</p>
<p>Primary Objective:</p> <ul style="list-style-type: none"> To compare the effect of BNC210 and placebo on the time course of resolution of agitation in hospitalised elderly patients as measured by the Pittsburgh Agitation Scale (PAS). <p>Secondary Objectives:</p> <ul style="list-style-type: none"> To compare the effect of BNC210 and placebo on the time course of change in global function in hospitalised elderly patients as assessed by the Clinical Global Impression Scale – Severity and Improvement (CGI-S/I). To assess safety and tolerability of BNC210 in hospitalised elderly patients with agitation. <p>Exploratory Objective:</p> <ul style="list-style-type: none"> To obtain preliminary estimates of pharmacokinetics of BNC210 in elderly patients.