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**ASX ANNOUNCEMENT**  
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## **Bionomics Reports Positive Data from Phase 1 Multiple Ascending Dose Trial of BNC210 for Anxiety and Depression**

- **All primary and secondary endpoints met, no adverse effects on cognition or emotional stability and no abuse potential indicated**
- **BNC210 reduced the effect of nicotine consistent with its mechanism of action**
- **Promising results support continued development of BNC210 as novel treatment for anxiety and depression**
- **Ongoing Phase 2 trial in patients with Generalized Anxiety Disorder anticipated to report data in Q3,2016**

Bionomics Limited (ASX:BNO, OTCQX:BNOEF), a biopharmaceutical company focused on the discovery and development of innovative therapeutics for the treatment of diseases of the central nervous system (CNS) and cancer, today reported positive data from the completed Phase 1 multiple ascending dose, placebo controlled clinical trial of BNC210, an orally administered negative allosteric modulator of the  $\alpha 7$  nicotinic acetylcholine receptor ( $\alpha 7$  receptor) being developed for the treatment of anxiety and depression. The results showed that BNC210 was safe and well-tolerated, and consistent with its mechanism of action at the  $\alpha 7$  receptor, showed that BNC210 significantly reduced the effect of nicotine as measured by electroencephalogram (EEG).

Dr. Philippe Danjou, Senior Director, Research and Development at Bionomics, said, "BNC210 has shown an encouraging safety and tolerability profile and the demonstration that BNC210 modulates nicotine-dependent changes as measured by EEG provides evidence of target engagement. These data support the continued development of BNC210 in this area of great unmet medical need".

In the study, a total of 54 healthy volunteers were enrolled and dosed for eight consecutive days, with 42 subjects receiving BNC210 (300mg - 2,000mg total dose per day) and 12 placebo. In addition to detailed safety evaluations, all study subjects underwent a standard battery of assessments measuring cognitive parameters. Subjective feelings produced by BNC210 were also assessed. Study results showed BNC210 was safe and well tolerated at all dose levels, and a maximum tolerated dose was not reached. No subject discontinued due to treatment-emergent adverse events. BNC210 administration did not result in adverse changes in cognition. The Bond & Lader Visual Analog Scales showed that there were no adverse changes in subjects' ratings of subjective feelings around alertness, contentedness or calmness and the Addiction Research

Centre Inventory 49 check-list (ARCI49) indicated that BNC210 administration did not result in feelings associated with drugs of abuse.

An additional pharmacodynamic test, the nicotine shift assay, was performed in subjects receiving either the highest dose of BNC210 or placebo. Subjects, all non-smokers, were administered nicotine by nasal spray with responses measured by EEG. Of the 30 subjects administered with nicotine prior to administration of either BNC210 or placebo, 13 responded to nicotine in a dose dependent manner. These nicotine responders were selected for analysis. When the study was unblinded, twelve of the nicotine responders received BNC210 whilst one nicotine responder received placebo. Eleven BNC210-treated subjects showed evidence of reduction in nicotine-induced EEG measures relative to baseline whilst one BNC210-treated subject and the placebo-treated subject showed no changes in nicotine-induced EEG measures. Overall BNC210 treatment significantly reduced EEG changes induced by half milligram incremental doses of nicotine from 0.5 to 2 mg ( $p < 0.02 - 0.0009$ ).

Bionomics' CEO & Managing Director Dr. Deborah Rathjen said "BNC210 exemplifies Bionomics' mission of discovering and developing proprietary, first in class drug candidates with the potential to significantly benefit patients. We believe BNC210 may offer differentiation from currently-approved drugs for the treatment of anxiety and depression".

"We look forward to progressing our current Phase 2 trial in patients with Generalized Anxiety Disorder and to considering other potential indications for BNC210 within the spectrum of anxiety disorders and depression. Anxiety and depression have overlapping symptoms and an estimated 40 percent of patients with depression also have anxiety." Dr Rathjen added.

Anxiety is a condition which places a considerable burden on our society. For example, approximately 14.4% of the Australian population is affected by anxiety. Approximately 40 million people suffer from anxiety disorders in the United States and patients with anxiety can have one or more anxiety disorders. There are six broad categories of anxiety disorders: generalized anxiety disorder, PTSD, panic disorder, social anxiety disorder, obsessive compulsive disorder and phobias. Generalized anxiety disorder is characterized by persistent, excessive, and unrealistic worrying about everyday things. Approximately 6.8 million people suffer from generalized anxiety disorder in the United States. The anxiety market is projected to reach US\$18.2 billion by 2020. There are a number of drugs used to treat anxiety with the mainstay being benzodiazepines. Generalized anxiety disorder is commonly treated with SSRIs and SNRIs which are antidepressants that enhance either serotonin or norepinephrine. The key limitations with SSRIs and SNRIs are a modest efficacy for many patients and late onset of action, discontinuation syndrome, changes in weight, sexual dysfunction and suicide ideation in adolescents, while benzodiazepines such as Valium display side-effects such as sedation, addiction, tolerance and cognitive disturbances, and are therefore not recommended for long-term treatment despite short-term efficacy.

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### **About BNC210**

BNC210 is a novel small molecule, orally-administered drug candidate being developed for anxiety and depression 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 and specific negative allosteric modulator of the  $\alpha 7$  nicotinic acetylcholine ( $\alpha 7$ ) receptor. Acetylcholine and the  $\alpha 7$  receptor are increasingly 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 center of the brain. To date, BNC210 has been evaluated in six completed clinical trials in 190 subjects.

### **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 focused on the treatment of serious central nervous system disorders and on the treatment of cancer. Bionomics' lead drug candidate BNC210, currently in Phase 2 for the treatment of generalized anxiety disorder, is a novel, proprietary negative allosteric modulator of the alpha-7 ( $\alpha 7$ ) nicotinic acetylcholine receptor. The Company is also developing BNC101, its lead humanized monoclonal antibody targeting a key receptor on cancer stem cells that is overexpressed in metastatic colorectal cancer, metastatic pancreatic cancer and many other solid tumours; BNC101 is expected to enter clinical trials in the fourth quarter of 2015. Bionomics has strategic partnerships with Merck & Co. in pain and cognition.

[www.bionomics.com.au](http://www.bionomics.com.au)

### ***Factors Affecting Future Performance***

This presentation contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this presentation that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' drug candidates (including BNC210 and BNC101), 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.

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