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# Bionomics Announces Positive Results from Phase 2 Trial of BNC210 in Generalized Anxiety Disorder

- Both primary endpoints met with a high level of significance; suggests potential for paradigm change for treatment of anxiety disorders
- BNC210 suppressed activation of the amygdala out-performing standard of care, lorazepam (Ativan)
- BNC210 caused significant changes in cerebral perfusion, measured by brain imaging, consistent with anti-anxiety activity
- Secondary endpoint met with a high level of significance; BNC210 suppressed anxietyrelated defensive behaviour in the Joystick Operated Runway Task, out-performing lorazepam
- Phase 2 results strengthen BNC210 licensing package and provide a significant boost to partnering prospects

Bionomics Limited (ASX: BNO, OTCQX: BNOEF), a clinical stage biopharmaceutical company focused on the discovery and development of innovative therapeutics for the treatment of diseases of the central nervous system and cancer, today announced positive top-line data from its Phase 2 clinical trial of BNC210, a novel, first in class, negative allosteric modulator of the  $\alpha$ 7 nicotinic acetylcholine receptor, in patients with Generalized Anxiety Disorder (GAD).

"These exciting Phase 2 data herald a potential paradigm shift for the treatment of anxiety disorders," commented Professor Allan Young, Director of the Centre for Affective Disorders at King's College London and Principal Investigator of the study. "This patient population is poorly served with current medications and BNC210, in contrast to benzodiazepines such as lorazepam, has shown no evidence of sedation or addictive potential," Professor Young added.

The single centre, double-blinded, placebo and lorazepam-controlled, 4-way cross-over Phase 2 clinical trial was conducted in 24 patients with untreated GAD. The objective of the study was to evaluate the capacity of BNC210 to engage brain systems relevant to anxiety while resting and in response to anxiety-related tasks. The co-primary endpoints were change in cerebral perfusion measured by arterial spin labelling and change in task-related brain activity, specifically in the amygdala as measured by functional Magnetic Resonance Imaging (fMRI) during the Emotional Faces Task (EFT).

The results of the study show that BNC210 induced statistically significant changes in cerebral perfusion (300mg BNC210, p<0.05) and also significantly reduced amygdala activation in response to fearful faces during the EFT (300mg BNC210, p<0.05). In comparison, lorazepam exerted a modest suppressive effect on amygdala activation during performance of the EFT (1.5mg lorazepam, p=0.069).

Extensive evidence indicates that the amygdala plays a major role in fear and anxiety reactions. The data from this study indicates that BNC210 may exert anti-anxiety effects in patients via suppression of amygdala activation.

Eminent world expert on brain imaging, Professor Steve Williams, commented "We are pleased to report that BNC210 causes a significant change in localized brain perfusion which reassures us that these doses of BNC210 are having a central effect and there is proof of target engagement".

A secondary endpoint of the trial was to determine the effect of BNC210 on defensive behaviour using the Joystick Operated Runway Task (JORT) which uses a force-sensing interface to obtain an objective measure of the intensity of threat avoidance motivation. BNC210 administration was associated with a significant decrease in the intensity of threat avoidance behaviour (300mg BNC210, p=0.007; 2,000mg BNC210, p=0.033). BNC210 outperformed lorazepam in this regard (1.5mg lorazepam, p=0.165).

Fear or anxiety result in the expression of a range of defensive behaviours, which are aimed at escaping from the source of danger or motivational conflict. The results of the JORT further support the anti-anxiety effect of BNC210.

Dr Adam Perkins, Lecturer in the Neurobiology of Personality at King's College London and developer of the JORT commented "These data show that BNC210 engages anxiety-related brain systems more effectively than lorazepam. Moreover, the neuroimaging results were backed up by the behavioural findings, as BNC210 also reduced the intensity of threat avoidance behaviour to a significant degree, once again out-performing lorazepam".

"The combined data from this trial support further development of BNC210 and give us confidence that the drug has the potential to bring relief to sufferers of anxiety and trauma and stress related disorders. We are currently recruiting for a Phase 2 trial in patients with post-traumatic stress disorder (PTSD) with this in mind. Today's ground-breaking data also greatly strengthen the BNC210 licensing package and provide a significant boost to partnering prospects," commented Dr Deborah Rathjen CEO & Managing Director of Bionomics.

"Anxiety disorders are a significant burden for our communities. Approximately 40 million adults suffer from anxiety in the U.S. and of these, it is estimated that 6.8 million suffer from GAD, a chronic illness. Every year in Australia, approximately 14 per cent of the population (1 in 7) experiences an anxiety disorder and 2.7 per cent experiences GAD. Nearly 6 per cent of the Australian population will experience GAD in their lifetime<sup>1</sup>. We are very excited that BNC210 may make a positive contribution to treatment options in the future," Dr Rathjen added.

The anxiety and depression treatments markets are projected to reach US\$18.2 billion by 2020<sup>2</sup> highlighting the significant market opportunity for BNC210. The future growth of the market would depend on commercialisation of novel drugs, such as BNC210, for new indications.

# **INVESTOR CONFERENCE CALL:**

Bionomics will today host an investor conference call to discuss the positive results from the phase 2 trial for BNC210 in treating Generalized Anxiety Disorder. The call has been scheduled for 4.30pm AEST (US PST 11.30pm / EST 2.30am; UK 7.30am).

Conference ID: 664149

#### Dial in details

Australia: 1800 908 299 or 02 9007 8048

#### International dial-in details:

These numbers are toll-free numbers for each country listed below. For countries not listed below, the Australian Participant Toll number listed above can be dialled.

 Canada/United States
 1855 624 0077

 China
 1080 0140 1776

 Hong Kong
 800 968 273

 India
 0000 800 321 8057

 Japan
 0066 3386 8000

 New Zealand
 0800 452 795

 Singapore
 800 101 2702

 United Kingdom
 0800 051 1453

To ask a question, participants will need to dial \*1 (start 1) on their telephone keypad.

1 Australian Bureau of Statistics. (2008). *National Survey of Mental Health and Wellbeing: Summary of Results, 2007.* Cat. no. (4326.0). Canberra: ABS.

2 Transparency Market Research (TMR), June 2015

### FOR FURTHER INFORMATION PLEASE CONTACT:

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### **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 development for the treatment of generalized anxiety disorder and for post-traumatic stress disorder, is a novel, proprietary negative allosteric modulator of the alpha-7 (α7) 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 entered clinical trials in the first quarter of 2016. Bionomics has strategic partnerships with Merck & Co., Inc (known as MSD outside the United States and Canada) in pain and cognition.

## 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 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.

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.

Subject to the requirements of any applicable legislation or the listing rules of any stock exchange on which our securities are quoted, we disclaim any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this announcement.