

ASX ANNOUNCEMENT 20 April 2015

# BIONOMICS INITIATES PHASE II CLINICAL TRIAL OF BNC210 FOR TREATMENT OF ANXIETY

**Bionomics Limited (ASX: BNO, OTCQX: BNOEF)**, a biopharmaceutical company focused on the discovery and development of innovative therapeutics for the treatment of cancer and diseases of the central nervous system, today announced the initiation of a Phase II clinical study of BNC210, the Company's drug candidate in development for the treatment of anxiety and depression.

The study will use functional magnetic resonance imaging (fMRI) to assess the effects of BNC210 on brain activity in patients suffering from anxiety.

"BNC210 has the potential to significantly improve the lives of anxiety sufferers, and we believe that with effective management of anxiety there is the potential to reduce the huge impact of the disease on societal and healthcare resources," said Dr. Deborah Rathjen, Bionomics' CEO and Managing Director.

"Currently, there is a large unmet medical need for fast-acting anxiolytic agents that lack the side effects observed with existing treatments, which include sedation and addiction, as well as negative side effects on memory and body movement. Bionomics' commitment to the rapid development of BNC210 is indicative of its significant potential as an improved therapeutic for the treatment of anxiety.

The double-blinded, placebo and lorazepam-controlled, four-way crossover single-centre Phase II study (BNC210.006) will be conducted in 24 patients with untreated Generalised Anxiety Disorder (GAD). Patients will be randomized to receive one of two doses of BNC210 (300mg or 2000mg) or one of two controls, placebo or 1.5mg Lorazepam. The study will evaluate the capacity of BNC210 to engage brain systems relevant to anxiety. The endpoints include both significant changes in cerebral perfusion and in task-related brain activity using the emotional faces task during fMRI. The study is being conducted by Principal Investigator, Professor Allan Young, at The Institute of Psychiatry, Psychology & Neuroscience (IoPPN) at King's College in London.

The clinical phase of the study is expected to be completed by Q2 2016 with results due in Q3 2016.

Bionomics is also conducting an ongoing Phase Ib multiple ascending dose study (BNC210.005) of BNC210 in healthy human male volunteers. This study is examining the safety and tolerability of multiple doses of BNC210, after repeat dosing for eight days, with secondary endpoints investigating the pharmacokinetic and pharmacodynamic profile of BNC210 and its effect on cognitive functions.

# **Clinical Trial Appendix**

UDY REFERENCE BNG	C210.006
con effe cha	indomised, double-blinded, placebo and lorazepam-trolled, four-way crossover, Phase II study to evaluate the cts of single oral administration of BNC210 on brain activity nges captured by functional magnetic resonance imaging in lts with Generalised Anxiety Disorder (GAD).
(A)	mary objectives:  To determine whether BNC210 causes significant changes in cerebral perfusion using Arterial Spin Labelling in the resting state.  To determine whether BNC210 causes significant changes in task-related brain activity using the emotional faces task during functional magnetic resonance imaging (fMRI).
- - - <u>Ex</u> To	condary objectives:  To determine the effect of BNC210 on defensive behaviour.  To determine whether BNC210 alters affective self-report in a way that is consistent with reduced anxiety.  To contribute safety and tolerability information on BNC210.  ploratory objective  determine the correlation between BNC210-related brain tivity changes and affective self-report.
	ble-blinded
leve mg	Idomised, four-way crossover, with the effects of two dose els of BNC210 being compared to those of placebo, and 1.5 lorazepam used as a positive control.  Iower BNC210 dose will be 300 mg. The upper dose will be 0 mg.
IAL SUBJECT NUMBER A SU	ufficient number of subjects will be enrolled to allow 24 apleting subjects.
NTROL GROUP Place	cebo and 1.5mg Lorezepam Positive Control
	e or female volunteers who are un-medicated but meet the eria for Generalised Anxiety Disorder
	Institute of Psychiatry, Psychology & Neuroscience, King's ege, London
PECTED DURATION Clin	ical portion to be completed in approximately 12 months.
Brai whe Lab Fun emc Run and	in activity will be assessed by fMRI under resting condition are functional connectivity and Continuous Arterial Spin elling as a measure of cerebral blood flow will be collected. ctional fMRI will also be used during different tasks: an otional faces task and a behavioural task (Joystick Operated naway Task). The Spielberger State-Trait Anxiety inventory a subjective scale assessment will also be used as outcome asures.
	2210 has been evaluated at single doses in 6 clinical trials 154 subjects to date  1. BNC210.001: Single Ascending Doses Study - Australia  2. BNC210.002: Fed and Fasted Study - Australia  3. BNC210.003: Lorazepam Comparison and EEG Study, cognition as primary end point - France  4. BNC210.004: CCK Challenge - France  5. Single Ascending Doses Study – USA
	4. BNC210.004: CCK Challeng

#### FOR FURTHER INFORMATION PLEASE CONTACT:

Bionomics Limited
Dr Deborah Rathjen
CEO & Managing Director
+618 8354 6101 /
0418 160 425
drathjen@bionomics.com.au

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

Stern IR
Beth DelGiacco
+1 212 360 1200
beth@sternir.com

#### **About BNC210**

BNC210 is a first-in-class compound for the treatment of anxiety that lacks the side effect profile of current therapies such as benzodiazepines, selective serotonin reuptake inhibitors and serotonin norepinephrine reuptake inhibitors. BNC210 works by negative allosteric modulation of the alpha 7 nicotinic acetylcholine receptor which is key target for anxiety. To date, BNC210 has been evaluated at single doses in six clinical trials with 154 subjects.

#### **About Bionomics Limited**

Bionomics (ASX: BNO) is biopharmaceutical company which discovers and develops innovative therapeutics for cancer and diseases of the central nervous system. Bionomics has small molecule product development programs in the areas of cancer, anxiety, memory loss and pain. Its oncology approach includes cancer stem cell therapeutics.

Bionomics' discovery and development activities are driven by its four proprietary technology platforms: MultiCore®, a diversity orientated chemistry platform for the discovery of small molecule drugs; ionX®, a set of novel technologies for the identification of drugs targeting ion channels for diseases of the central nervous system; Angene®, a drug discovery platform which incorporates a variety of genomics tools to identify and validate novel angiogenesis targets (involved in the formation of new blood vessels); and CSC Rx Discovery™, which identifies antibody and small molecule therapeutics that inhibit the growth of cancer stem cells. These platforms drive Bionomics' pipeline and underpin its established business strategy of securing partners for its key compounds. Bionomics partners include Merck & Co.

## 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 presentation that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' development candidates BNC105, BNC210, BNC101 and BNC420, our acquisitions of Eclipse Therapeutics and Prestwick Chemicals and ability to develop products from their platforms, its licensing deals with Merck & Co, drug discovery programs and pending patent applications 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 risks related to our available funds or existing funding arrangements, a downturn in our customers' markets, our failure to introduce new products or technologies in a timely manner, regulatory changes, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantages, as well as other factors. Results of studies performed on competitors products 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 presentation.