

ASX ANNOUNCEMENT 2 February 2015

# BIONOMICS BEGINS PHASE 1B STUDY WITH ANXIETY DRUG BNC210

- Trial to accelerate development of BNC210 after reacquisition
- Commencement of Phase 2a trial to follow during Q1, 2015
- Clinical trials to pave the way for partnering opportunities

Bionomics Limited (ASX:BNO) has initiated a Phase 1b clinical trial in healthy volunteers of BNC210, the Company's drug candidate in development for the treatment of anxiety and depression.

The trial will be conducted by Biotrial International at its facility in Rennes, France and will investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of BNC210. This is a randomised, double-blind, placebo-controlled trial and will treat over 50 healthy male volunteers in sequential multiple ascending doses.

Four groups of subjects will be enrolled to receive one of four doses of BNC210 or placebo, twice a day for eight days.

Target engagement by BNC210 will be investigated through the use of a nicotine challenge where the subjects response to nicotine will be monitored by a brain EEG. All subjects on the study will undergo a standard battery of pharmacodynamic assessments.

The primary endpoint of the trial will be the safety and tolerability of BNC210 following multiple administrations with secondary endpoints investigating the pharmacokinetic and pharmacodynamic profile of BNC210 and its effect on cognitive functions and the response to nicotine.

In addition a Phase 2a study for BNC210 in human patients suffering anxiety is planned with the trial anticipated to commence during Q1, 2015 in the UK. These trials mark vital steps in the development of BNC210 and will position it for partnering opportunities.

"We're eager to get back to the clinic with BNC210 and unlock the potential of this compound," said Dr Deborah Rathjen, Bionomics' CEO and Managing Director.

"We expect this to be a pivotal year in its development and given the data thus far are confident it will be another Bionomics drug candidate that will attract the interest of big pharma companies."

Data from this trial is anticipated in Q3, 2015.

BNC210 is a first-in-class compound for the treatment of anxiety that appears to be devoid of the considerable side effect problems of current therapies. Its mechanism of action is by negative allosteric modulation of the alpha 7 nicotinic acetylcholine receptor, a novel target for anxiety. It has been evaluated at single doses in five clinical trials and 148 subjects to date.

As previously announced, financing for the clinical trials is in place through Silicon Valley Bank.

## **CLINICAL APPENDIX**

NAME	BNC210.005
PRIMARY ENDPOINT	Safety and tolerability of multiple ascending oral doses of BNC210 in healthy adult male subjects
SECONDARY ENDPOINTS	Preliminary pharmacokinetic profile of multiple ascending doses of BNC210
	Pharmacodynamic profile of multiple ascending oral doses of BNC210 on cognitive functions
	Pharmacodynamic profile of multiple administrations of the highest dose on nicotine shift
BLINDING STATUS	Double-blinded
TREATMENT METHOD	Four groups of subjects will be enrolled to receive one of four oral doses of BNC210 or placebo, twice a day for eight days
TRIAL SUBJECTS	50+
CONTROL GROUP	Randomised
SUBJECT SELECTION CRITERIA	Healthy males aged 18-60
TRIAL LOCATION	Biotrial International – Rennes, France
EXPECTED DURATION	Approximately six months
ADDITIONAL INFORMATION	All subjects on the study will undergo a standard battery of pharmacodynamic assessments measuring cognitive parameters: Choice Reaction Time, Digit Vigilance, Rapid Visual Information Processing, Learning Memory Task, Numeric Working Memory and Spatial Working Memory, or subjective feelings produced by the drug: Bond and Lader Visual Analogue Scale, and Addiction Research Centre Inventory (ARCI) 49  An additional pharmacodynamic test, the nicotine shift assay, will be performed in the cohort receiving the highest dose. Subjects will be administered nicotine (by nasal spray) which is known to produce a signature response in EEG recordings. BNC210 acts through a mechanism which may produce a shift in the nicotine response and so indicate target engagement.
CLINICAL TRIAL HISTORY	BNC210 has been evaluated at single doses in five clinical trials and 148 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
	<ol><li>Single Ascending Doses Study with BNC210 in a capsule – USA</li></ol>

## FOR FURTHER INFORMATION PLEASE CONTACT:

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#### **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 as well as vascular disruption in solid tumours.

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<sup>TM</sup>, 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 BNC375, our acquisition of Eclipse Therapeutics and ability to develop products from their platform, 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, Merck's decisions to continue or not to continue development of partnered compounds, 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.

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