

ASX ANNOUNCEMENT 30 March 2011

# BIONOMICS ANTI-ANXIETY DRUG PHASE Ib CLINICAL TRIALS SUCCESSFUL RESULTS

- BNC210 significantly reduced panic symptoms and faster than placebo
- Brain activity in trial subjects measured by EEG indicates anxiolytic activity by BNC210 and no sedation
- BNC210 clearly outperformed comparator Lorazepam in tests measuring attention, memory, co-ordination, sedation and addiction
- BNC210 administered to 108 healthy subjects with excellent safety profile

**30 March 2011, Adelaide, Australia:** Bionomics Limited (ASX: BNO) (ADR: BMICY) has successfully concluded two Phase Ib clinical trials of BNC210 which is being developed as a new generation treatment for anxiety and depression.

The two trials of BNC210 were initiated in France in October 2010 following approval by the French Medical Agency AFSSAPS (Agence Francaise de Securite Sanitaire des Produits de Sante) and the Ethics Committee of the Strasbourg Hospital, CPP (Comité de Protection des Personnes). Both trials were conducted by Forenap Pharma.

The first trial evaluated the effect of BNC210 on panic symptoms induced by pharmacological means in healthy volunteers. Panic attacks were induced by administration of the peptide CCK-4 and the severity of panic symptoms was assessed using the Panic Symptom Scale (PSS). Fifty-nine subjects were enrolled in the trial. Fifteen subjects were classified as having a panic attack upon CCK-4 administration.

BNC210 reduced both the total PSS score (total symptoms) and the intensity of symptoms in subjects when measured 10 minutes after the induction of a panic attack. With BNC210 treatment the number and intensity of symptoms decreased faster than with placebo and this reduction in symptoms was significant (p<0.05 for both the total symptom score and the intensity of symptoms). There was a strong, positive trend on the emotional stability of subjects suffering a panic attack which was associated with BNC210 treatment. BNC210 treated subjects returned to normal emotional status within 10 minutes of the administration of CCK-4 compared to 60 minutes on placebo. This trend correlated with the statistically significant reduction in panic symptoms by BNC210.

The second trial compared BNC210 with Lorazepam (a Valium-like anti-anxiety drug) on measures of attention, memory, co-ordination, addiction and sedation. This trial also compared the effects of BNC210 and Lorazepam on the brain using electroencephalography (EEG). Twenty-four subjects were enrolled in the trial with twenty-one subjects evaluated.

An important finding was that EEG data showed for the first time BNC210-related changes in human brain activity indicative of efficacy. The changes in brain activity induced by BNC210 were clearly differentiated from those observed following treatment of subjects with

Lorazepam, particularly in activity associated with sedation suggesting that BNC210 activity occurs in the absence of sedation.

In addition, the trial results confirmed the lack of debilitating side-effects of BNC210 relative to Lorazepam. While Lorazepam adversely affected attention, co-ordination and memory, BNC210 showed no evidence of these side-effects. Lorazepam also induced sedation as measured by the Karolinska Sleepiness Scale and showed evidence of addiction where treatment with Lorazepam was associated with LSD and phenobarbital/alcohol groups on the Addiction Research Centre Inventory 49 (ARCI49) scoring system. Testing of the same subjects following administration of BNC210 showed no evidence of sedation or indicators of addiction.

The BNC210/Lorazepam comparative side-effect profile is summarised in the following table. The EEG data is shown in the Clinical Appendix which follows this announcement.

	No Reduction in Attention	No Effect on Co- ordination	No Sedation	No Memory Impairment	No Addiction
BNC210	<b>√</b>	V	<b>√</b>	V	<b>√</b>
Lorazepam	Х	х	X	Х	Х

It is anticipated that data from both trials will be presented at major international scientific conferences later this year.

Bionomics CEO and Managing Director Dr Deborah Rathjen commented, "We are thrilled to report the positive results of both BNC210 clinical trials. The results have exceeded our expectations."

"Both studies were designed to demonstrate the value of BNC210 as an innovative new generation treatment for anxiety and depression and the results confirm the drug's potential. Anxiety is a common debilitating condition that affects 19 million patients in the US and anxiety drugs have an estimated worldwide market of up to US\$12 billion per annum. Blockbuster drugs that treat anxiety include Valium, Prozac and Effexor. 2009 worldwide sales of Effexor alone were US\$3.25 billion. These drugs are not ideal and BNC210 represents a next generation treatment for anxiety which stands out as free of the serious side-effects."

"The results of the CCK-induced panic trial have given the first indication of efficacy by BNC210 in humans and this result has been supported by the data coming from the second trial which gave indications of brain activity induced by BNC210 consistent with anxiolysis. This is a substantial step forward for BNC210 which presents a very compelling opportunity," Dr Rathjen said.

Professor Paul Fitzgerald of the Monash Alfred Psychiatry Research Centre, Alfred Hospital and Monash University School of Psychology and Psychiatry, commenting on the clinical trial

results said, "The data are very encouraging and point to BNC210 reducing anxiety in a manner that is potentially better for patients than current treatments. The EEG data indicates that BNC210 gets into the brain and exerts a more subtle and specific effect than Lorazepam. In addition, subjects recovered more quickly from a CCK-induced panic attack returning to a normal emotional state after 10 minutes when receiving BNC210. On placebo the subjects took around an hour to return to a normal emotional state after the panic attack."

Dr Sue O'Connor, BNC210 Project Leader since the inception of the project, commented, "I am delighted that we saw data from human trials consistent with data from our animal studies in that BNC210 clearly lacks the side-effects of sedation, memory impairment and reduction of co-ordination shown by drugs of the benzodiazepine class."

"For the first time in humans we also have an indication that BNC210 treatment does not give rise to indicators of addiction," Dr O'Connor added.

Commenting on the outlook for Bionomics, Dr Rathjen noted, "We are also expecting results from our ongoing renal cancer and mesothelioma clinical trials of BNC105 later this year."

"We will continue to execute Bionomics' established business strategy including securing partners for our key compounds. Bionomics' Board believes the Company has an exciting independent future and today's results are an important milestone in delivering value for our shareholders."

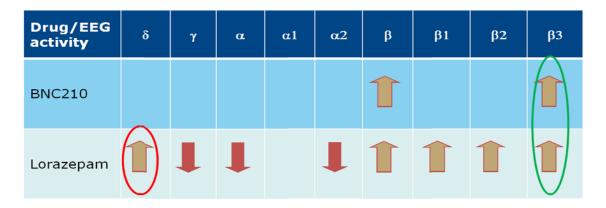
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### Clinical Appendix

## BNC210-Induced changes in brain activity measured by EEG indicate anxyolysis in the absence of sedation.



EEG data showed that BNC210 caused some changes in brain activity similar to those of Lorazepam which may be indicative of efficacy as a treatment for anxiety as shown by the green circle.

The EEG signature of BNC210 was clearly differentiated from that observed following treatment of subjects with Lorazepam however, particularly in activity associated with sedation (indicated by the red circle). Unlike Lorazepam, BNC210 did not increase activity in the  $\delta$  region suggesting that BNC210 activity occurs in the absence of sedation.

### **About Bionomics Limited**

Bionomics (ASX: BNO) is a leading international biotechnology 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, epilepsy and multiple sclerosis. BNC105, which is undergoing clinical development for the treatment of cancer, is based upon the identification of a novel compound that potently and selectively restricts blood flow within tumours. A clinical program is also underway for the treatment of anxiety disorders and depression based on BNC210 which has recently completed Phase Ib clinical trials. Both compounds offer blockbuster potential if successfully developed.

Bionomics' discovery and development activities are driven by its three technology platforms: 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). MultiCore® is Bionomics' proprietary, diversity orientated chemistry platform for the discovery of small molecule drugs. ionX® is a set of novel technologies for the identification of drugs targeting ion channels for diseases of the central nervous system. These platforms underpin Bionomics' established business strategy and Bionomics is committed to securing partners for its key compounds.

For more information about Bionomics, visit 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 press release that relate to prospective events or developments 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 the clinical evaluation of either BNC105 or BNC210, 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. 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 press release.