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## ASX ANNOUNCEMENT

27 October 2009

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### FIRST STAGE OF BNC210 CLINICAL TRIAL SUCCESSFULLY COMPLETED

- **BNC210 is safe and well tolerated at doses that achieve drug blood levels consistent with suppression of the symptoms of anxiety in preclinical models**
- **The observed pharmacokinetics support potential for once a day oral administration of BNC210**

**Adelaide, Australia:** Bionomics Limited (ASX: BNO) today announced the completion of the first stage of its current Phase I clinical trial of BNC210 which is being developed for the treatment of anxiety disorders.

The Phase I clinical trial is being conducted in groups of healthy male volunteers at the Pain and Anaesthesia Research Clinic (PARC) within the Royal Adelaide Hospital. The primary objectives of the trial, to evaluate the safety, tolerability and the pharmacokinetics of BNC210, have been met.

BNC210, in doses up to and including 1200mg, was safe and well tolerated with no clinically significant adverse events reported. In addition, the administered doses of BNC210 achieved blood levels consistent with the anxiolytic activity of BNC210 observed in preclinical models of anxiety.

Having met the key objectives of oral bioavailability and safety at dose levels that equate to preclinical activity, Bionomics will seek approval to progress to the next stage of the clinical trial in order to delineate the full spectrum of BNC210 safety through evaluation of higher dose levels. The potential effects of BNC210 on mood and anxiety levels will also be assessed as a secondary objective in the healthy volunteers. It is anticipated, pending approval to continue the clinical trial, that it will be completed by the end of 2009.

Anxiety is a common debilitating condition that affects 40 million patients over the age of 18 years in the US alone, and has an estimated market value of up to US\$15 billion worldwide.

The Principal Investigator on the trial Paul Rolan, Professor of Clinical Pharmacology at the University of Adelaide and a co-founder of PARC commented "The first clinical testing of BNC210 in man has made important progress with the confirmation that the drug is orally bioavailable, with drug levels being measured in blood that are consistent with levels which show suppression of the symptoms of anxiety in preclinical models. To date it is remarkably well tolerated and it is intended that this will be tested further in the next stage of the trial. There have been no fundamentally new and effective treatments for anxiety for decades. Of the treatments we do have, many patients are burdened by side-effects".

Dr Gabriel Kremmidiotis, Bionomics VP Discovery Research said, "It is very satisfying to see that BNC210 has been de-risked with the initial clinical data confirming that it is absorbed when given to humans. We will seek approval for the drug to continue with dose escalation in the next stage of the clinical trial with the objective of identifying central nervous system (CNS) effects. We are very encouraged by the results of our preclinical studies of BNC210 which has demonstrated efficacy across a broad range of models of anxiety".

Approval for the first stage of the trial was granted by the Research Ethics Committee of the Royal Adelaide Hospital in May 2009 and notification given to the Australian regulatory body, the Drug and Safety Evaluation Branch of the Therapeutic Goods Administration (TGA). The same approval process will be used for Stage 2 of the trial. The trial design is in accordance with the principles of the International Conference on Harmonization (ICH), standards of conduct for clinical trials that are essentially uniform for all the major regulatory agencies world-wide, including the FDA and Australia's TGA.

The potent anxiolytic activity of BNC210 and lack of side effects has been identified in extensive preclinical studies across a broad range of models. Current anxiety treatments, such as benzodiazepines (Valium) and selective serotonin reuptake inhibitors (SSRIs, e.g., Prozac), have various side effects associated with their use. Benzodiazepines offer acute relief to people suffering from anxiety but have sedative, cognitive and motor impairing side effects. In addition, their protracted use can result in tolerance and addiction. SSRIs exhibit slow onset of action and are associated with side effects such as early agitation, gastric disturbances, and sexual dysfunction which preclude their use for the long-term management of anxiety disorders.

#### **FOR FURTHER INFORMATION PLEASE CONTACT:**

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##### **About Bionomics Limited**

Bionomics (ASX: BNO) 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. Bionomics' most advanced program, BNC105 for the treatment of cancer, is based upon the identification of a novel compound that potently and selectively restricts blood flow within tumours. Bionomics' discovery and development activities are driven by its three technology platforms: Angene®, the company's angiogenesis target and drug discovery platform, incorporates a variety of genomics tools to identify and validate novel angiogenesis targets. 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.

For more information about Bionomics, visit [www.bionomics.com.au](http://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 BNC105 and 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.*