

# ASX ANNOUNCEMENT 7 June 2010

# **Bionomics Presents BNC105 Clinical Data at ASCO**

- Presentation of results from the BNC105 Phase I dose escalation study in patients with a range of solid tumours.
- Results underpin the rationale of the current Phase II trials of BNC105 in renal cancer and mesothelioma.

**7 June 2010; Adelaide, Australia:** Bionomics Limited (ASX: BNO) today announced the presentation of data from its first-in-human trial for its anti-cancer compound BNC105 at the annual American Society of Clinical Oncology (ASCO) conference in Chicago, Illinois. Dual acting BNC105 is a vascular disrupting agent and an inhibitor of cancer cell proliferation.

Bionomics has chosen to present data at ASCO, a prestigious forum strongly focused on patient-oriented clinical research. The Phase I dose escalation study was conducted in patients with different solid tumours, including colorectal carcinomas, head and neck cancers, renal cell cancer and mesothelioma.

The data shows that BNC105P (the pro-drug form of BNC105) was well tolerated without any serious adverse side effects below the maximum dose of 18.9 mg/m². Stable disease was observed in 4 of 16 patients who completed at least two cycles of treatment at doses of 8.4 mg/m² or higher. A dose of 16 mg/m² has been selected for Phase II trials which are now underway for renal cancer and mesothelioma (one patient with renal cancer and one with mesothelioma experienced disease stabilization in the Phase I study).

The plasma concentration of the drug generally increased in proportion to the dose, with an average half-life of less than one hour. Drug activity was evidenced by vascular shutdown in DCE-MRI images of the tumors post-treatment.

Biomarker analysis in patient blood samples indicated changes consistent with the BNC105 mechanism of action. Specifically, tubulin levels were reduced in patients receiving doses of BNCI05P at 12.6mg/m2 and above. This indicates that the drug was acting on its intended molecular target.

Dr Deborah Rathjen, CEO & Managing Director of Bionomics, said "the publication of the outcomes of the successful Phase I trial strengthens confidence in the ongoing development of BNC105 and underpins the rationale of the Phase II trials that are currently in progress. We are very excited by the potential of this drug and anticipate initial Phase II data being available as early as the end of this year for the renal cancer trial and in the first half of calendar year 2011 for mesothelioma".

"BNC105 has the potential to treat all solid tumour types. But by selecting renal cell cancer and mesothelioma as the first Phase II clinical trial indications for BNC105, Bionomics has selected cancer indications which have a fast path to market. For example renal cancer was the market entry indication for Sutent (Pfizer) and similarly mesothelioma for Alimta (Lilly). Both are blockbuster drugs with 2009 sales of US\$964 million and US\$1.7 billion respectively", explained Dr Rathjen.

Bionomics' poster gives comprehensive details from the study including patient demographics, their disease characteristics, number of doses received, clinical benefit and tolerance of the treatment. The poster presentation is available on Bionomics' website.

Details of the scheduled poster presentation and the ASCO abstract are shown below:

Title: A first-in-human, phase I pharmacodynamic (PD) and pharmacokinetic (PK) study of BNCI05P, a novel vascular disrupting agent (VDA) and inhibitor of cancer cell proliferation.

Session Category: Developmental Therapeutics - Experimental Therapeutics

Sub-category: Vascular Targeting

Session: Monday June 7, 8:00 AM to 12:00 PM

Location: S Hall A2

# FOR FURTHER INFORMATION PLEASE CONTACT:

#### **Bionomics Limited**

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# **About ASCO**

ASCO was founded in 1964 and is the world's leading professional organization representing physicians who treat people with cancer. The ASCO annual meeting is considered the premier international forum for the presentation of scientific research and state-of-the-art education in clinical oncology. The five-day event attracts 30,000 attendees from around the world. Clinical trial results and updates presented at ASCO's annual meeting represent the significant progress made each year in the fight against cancer.

### **About Bionomics Limited**

Bionomics (ASX: BNO) is a leading international drug discovery and development company. It 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 based on BNC210 which exhibits strong anxiolytic activity without side effects in preclinical models. 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.

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 BNCl05 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.