

ASX ANNOUNCEMENT 3 February 2012

# BNC105 RENAL CANCER TRIAL DATA PRESENTED AT ASCO-GU

- BNC105 has the potential to represent an entirely new treatment paradigm for patients with renal cancer
- BNC105 is a novel compound being developed by Bionomics as a Vascular Disruption Agent (VDA) for treatment of solid tumour cancers
- Over 100,000 people die of renal cancer in the world each year; it is the 7th most common form of cancer
- Clinical data supports the use of the combination of Afinitor and BNC105 which is safe and well tolerated

Bionomics Limited (ASX: BNO) (ADR: BMICY) announced that BNC105 clinical trial data in patients with progressive metastatic renal cancer will be presented at the American Society for Clinical Oncology 2012 Genitourinary Cancers Symposium meeting (ASCO-GU) in San Francisco.

Bionomics is conducting a US multi-centre Phase II clinical trial of BNC105 in combination with everolimus (Afinitor) in patients with metastatic Renal Cell Carcinoma (RCC). Afinitor is an mTOR inhibitor, which is used as a treatment after patients have failed therapy with Tyrosine Kinase Inhibitors (TKI). Afinitor, which was approved by the FDA for the treatment of renal cancer in 2009 and is marketed by global Pharma company Novartis, had sales of US\$310 million in the nine months to 31 September 2011.

This poster presentation, to be given by the Principal Investigator, Dr Thomas E Hutson of the Texas Oncology-Baylor Charles A. Sammons Cancer Center, details the results of the Phase I component of the clinical trial which was completed in 2011.

The Phase II component of the study is currently underway and more than 21 US-based clinical trial sites have been activated to date. The primary objective of the Phase I component of the clinical trial was to examine the safety and tolerability BNC105 in combination with Afinitor.

Twelve patients were enrolled to the Phase I component. A number of patients had completed over 10 cycles of treatment with the BNC105 and Afinitor combination at the time of completion of the Phase I component of the trial and five patients remained on treatment. Currently one patient has completed 15 cycles of treatment and three patients remain on treatment.

The results indicate that the recommended dose of Afinitor is well tolerated when combined with the previously identified Phase II dose level of BNC105 of 16 mg/m², supporting the use of Afinitor and BNC105 at their full dose levels.

Plasma pharmacokinetic analysis of drug levels indicated no interaction between BNC105 and Afinitor, confirming the compatibility of the drug combination.

As a Vascular Disruption Agent (VDA), BNC105 rapidly shuts down existing and new tumour blood vessels with no effect on normal blood vessels.

The conduct of the RCC clinical trial is aligned with Bionomics' Phase II partnership strategy for BNC105. Data from the RCC trial and the planned clinical trial of BNC105 in women with ovarian cancer may enable consideration by the FDA of fast track designation for BNC105 adding substantial value to the BNC105 licensing package.

Key poster information:

Session Title: General Poster Session E: Renal Cancer Session

Date: Saturday, February 4, 2012

Time: 6:45am - 7:55am and 11:50am - 1:05pm

Location: San Francisco Marriott Marquis, Golden Gate Hall

Abstract Number: 373

Title: Phase I/II study of a BNC105P/everolimus regimen for progressive metastatic renal cell carcinoma (mRCC) following prior tyrosine kinase inhibitors (Hoosier Oncology Group).

Poster Board Number: B10

The poster can be accessed on the Bionomics website www.bionomics.com.au

### FOR FURTHER INFORMATION PLEASE CONTACT:

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#### **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. BNC105 offers blockbuster potential if successfully developed. A clinical program is also underway for the treatment of anxiety disorders and depression based on BNC210, a novel compound which stimulates neurite outgrowth. BNC210 is partnered with Ironwood Pharmaceuticals. Bionomics has a partnered program with Merck Serono for new treatments for multiple sclerosis and other autoimmune disorders.

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

# **About Renal Cell Carcinoma (RCC)**

RCC is the most common form of cancer that originates in the kidney. RCC occurs due to mutations of cells in the kidney's filtering system. Worldwide over 100,000 people die of RCC each year and it is the seventh most common cancer and tenth most common cause of cancer-related deaths among men. About 2-3% of all cancers are renal cell carcinomas.

The number of RCC diagnoses is increasing by close to 2% per year. In Australia there are just over 2,000 new cases of primary kidney cancer diagnosed each year. Australians have a one in 74 risk of developing RCC during their lifetimes. Kidney cancer caused 855 deaths in Australia in 2007 (539 men, 316 women), accounting for 0.6% of all deaths. Primary kidney cancer is mostly a disease seen in adults over 40 and the disease is rare in children.

### 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, its Merck Serono alliance, its licensing deal with Ironwood Pharmaceuticals, 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.