

# ASX ANNOUNCEMENT 3 June 2013

## **BNC105 TRIALS PRESENTED AT ASCO**

- Recruitment into Phase I ovarian cancer trial completed
- Phase I renal cancer trial data indicative of clinical benefit

Bionomics Limited (ASX: BNO) (ADR: BMICY) will provide an update on its BNC105 clinical trial program at the annual American Society for Clinical Oncology (ASCO) meeting in Chicago, Illinois on Monday 3<sup>rd</sup> June.

#### **Renal Cancer Trial**

Bionomics is conducting a multinational, multi-centre Phase I/II clinical trial of BNC105 in combination with everolimus (Afinitor) in patients with progressive metastatic renal cell carcinoma that have previously progressed on treatment with tyrosine kinase inhibitors. Afinitor is an mTOR inhibitor used as a treatment after patients have failed therapy with tyrosine kinase inhibitors such as Sutent. Afinitor, approved by the FDA for the treatment of renal cancer in 2009 and marketed by global pharma company Novartis, had sales of US\$700 million in 2012.

The poster being presented by Dr John Sarantopoulos of the Institute for Drug Development Cancer Therapy & Research Centre, University of Texas Health Science Centre, San Antonio provides an update and additional data from the Phase I component of the trial.

Phase I data are indicative of clinical benefit and sustained therapy, with patients staying on therapy for up to 18 months. The combination of BNC105 and Afinitor is well tolerated with no dose limiting toxicities or evidence of cumulative toxicity. Eight of the 12 patients achieved disease stabilization. The median treatment period across these 8 patients was 11 cycles. Dose related changes in biomarkers indicative of vascular response suggest that BNC105 reaches plasma levels of pharmacological significance.

The Phase II component of the study is ongoing at 77 US, Australian and Singaporean clinical trial sites.

## **Ovarian Cancer Trial**

Bionomics is conducting a multinational multi-centre Phase I/II clinical trial to evaluate BNC105 in combination with current standard therapy of carboplatin and gemcitabine in patients with ovarian cancer who previously responded to but progressed whilst on treatment with platinum agents.

Recruitment into the Phase I component of the trial has been completed.

The study is being conducted by the Australian and New Zealand Gynaecological Oncology Group (ANZGOG) working with the National Health and Medical Research Council Clinical Trials Centre (NH&MRC CTC) in Australia and the Hoosier Oncology Group in the United States. The poster presentation will be given by the Principal Investigator, Dr Danny Rischin of Peter MacCallum Cancer Institute, Melbourne, Australia.

## **Key poster information:**

	Renal	Ovarian	
Presentation Title:	A phase I/II trial of BNC105P with everolimus in metastatic renal cell carcinoma (mRCC) patients: Updated phase I results of the DisrupTOR-1 trial.	A phase I/II study of the vascular disrupting agent BNC105P in combination with gemcitabine-carboplatin in partially platinumsensitive ovarian cancer patients in first or second relapse: An international collaborative group trial of ANZGOG and HOG.	
Poster No:	4563	TPS5612	
Category :	Genitourinary (Nonprostate) Cancer	Gynecologic Cancer	
Sub-category:	Kidney Cancer	Ovarian Cancer	
Session Type:	General Po	General Poster Session	
Location:	SH	S Hall A2	

#### FOR FURTHER INFORMATION PLEASE CONTACT:

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## **About Bionomics Limited**

Bionomics (ASX: BNO) is an Australian based international biotechnology company which discovers and develops innovative therapeutics for cancer and diseases of the central nervous system. Bionomics has small molecule and antibody product development programs in the areas of cancer, anxiety, and memory loss. Its oncology approach includes cancer stem cell therapeutics as well as vascular disruption in solid tumours.

BNC105, which is undergoing Phase II clinical development in a range of solid tumour types, 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 IW-2143(BNC210), a novel compound which stimulates neurite outgrowth. IW-2143 is partnered with Ironwood Pharmaceuticals.

Bionomics' discovery and development activities are driven by its four proprietary 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®, 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; 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. 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, IW-2143 (BNC210), BNC101 and BNC375, our acquisition of Eclipse Therapeutics and ability to develop products from their platform, 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, Ironwood's decisions to continue or not continue development of IW-2143, 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 announcement.