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ASX ANNOUNCEMENT
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Bionomics completes enrolment for BNC105 Phase II renal cancer trial

- **Phase II trial key milestone in advancing program to partnership**
- **BNC105's innovative approach targets significant market**
- **135 patients enrolled across US, Australia and Singapore**

Bionomics Limited (ASX: BNO) has completed enrolment into a randomized Phase II clinical trial testing the combination of BNC105 plus everolimus (Afinitor) to treat patients with advanced renal cell carcinoma, the DisrupTOR-1 clinical trial.

This is the first and only randomized trial to test the combination of an mTOR inhibitor (Afinitor) with a vascular disrupting agent (BNC105) in renal cancer.

CEO and Managing Director, Dr Deborah Rathjen said, "The enrolment of 135 patients into this first Phase II clinical trial of BNC105 is an important achievement for Bionomics. It is particularly exciting to reach this milestone in a trial which has the potential to create a new paradigm for the treatment of renal cancer. We have always said that we would be looking to partner this program once we had sufficient data from our clinical trials and achieving this milestone is an important step in the path to partnership. When the time is right, we hope to strike a strategic deal that will allow us to advance this compound through to market and deliver new hope to patients suffering from renal cancer."

Speaking about the effectiveness of BNC105 Dr José Iglesias, Chief Medical Officer of Bionomics said, “The mechanism of action of BNC105 provides an innovative approach to the treatment of solid tumours, including metastatic renal cell carcinoma, by attacking established tumour vasculature. We believe that there is a strong scientific rationale for this combination, as well as compelling preclinical and Phase I data that support this approach. Afinitor and BNC105 work by different but complementary mechanisms of action. The vascular disrupting effect of BNC105 causes hypoxic stress and Afinitor concurrently blocks the mTOR driven recovery pathway of renal tumours."

“We are grateful to the patients involved in this trial and thank them and their families. Treatment options remain limited in progressive metastatic renal cell cancer for patients who have failed tyrosine kinase inhibitor therapy and BNC105 has the potential to broaden treatment options for these patients”, said Dr Iglesias.

This Phase II trial was conducted at sites across the US, Australia and Singapore and enrolled 135 patients with advanced metastatic renal cell carcinoma. Patients, who had failed prior therapy with

tyrosine kinase inhibitors such as Sutent, were randomized into one of two treatment arms: one arm to receive Afinitor, and the second arm to receive Afinitor plus BNC105. Once enrolled, patients are treated until disease progression or until adverse effects prohibit further therapy.

The human cost of renal cell carcinoma is substantial with the disease accounting for approximately 85 per cent of kidney cancers. Every year approximately 200,000 cases are diagnosed worldwide, with 55,000 people diagnosed in the US alone. The five year survival rate for patients with metastatic disease is less than 2 per cent. The cost of treating the disease is also significant with the market for drugs targeting renal cell carcinoma estimated at $2.5 billion per annum. In 2012 the sales of Afinitor were $700 million.

Further details of the trial are shown below in the clinical appendix and can also be found at www.clinicaltrials.gov which provides details of all approved clinical trials being conducted in the US.

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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™, 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.

Clinical Appendix

Study Title: BNC105 in combination with Afinitor® (everolimus) or following everolimus for progressive metastatic clear cell renal cell carcinoma following prior tyrosine kinase inhibitors.

Study Design: This is a trial to evaluate the combination of BNC105 and everolimus for the therapy of progressive clear cell renal cell carcinoma following prior treatment with tyrosine kinase inhibitor(s) (Arm A). Additionally, patients progressing on everolimus alone will be offered BNC105, which will provide an opportunity to evaluate the activity of monotherapy with BNC105 (Arm B). Patients will be randomized 1:1 to either Arm A or Arm B of the study

Patients administered BNC105 will be treated in repeating 21-day cycles, each cycle consisting of two doses administered one week apart (i.e., on Days 1 and 8). Everolimus is orally administered as a 10 mg tablet once a day. The trial is being run under a U.S. FDA Investigational New Drug application.

Study Summary: The purpose of this study is to determine whether BNC105 in combination with/following everolimus is effective in the treatment of progressive metastatic renal cell carcinoma following prior tyrosine kinase inhibitors.

Endpoints:

PRIMARY

- Improvement in 6-month progression free survival (PFS) with the addition of BNC105 to everolimus.

SECONDARY

- Response rate with combination therapy compared to everolimus alone.
- PFS with BNC105 alone in patients progressing on everolimus.
- The adverse events of the everolimus and BNC105 when administered as a combination or sequential regimen.
- Overall survival.

EXPLORATORY

- To determine the correlation of PFS with biomarkers.