



ABN 53 075 582 740

## ASX ANNOUNCEMENT

2 July 2009

---

### BIONOMICS TO UNDERTAKE US CLINICAL TRIAL OF BNC105 IN RENAL CELL CANCER

**Adelaide, Australia:** Bionomics Limited (ASX:BNO) today announced that two key milestones have been reached in the clinical development of BNC105, its novel vascular disrupting agent (VDA) for the treatment of solid tumour types:

- A dose of 12.6 mg/m<sup>2</sup> has been selected for the next clinical trial of BNC105, and
- The company has engaged Hoosier Oncology Group, Inc (HOG), headquartered in Indianapolis, IN (USA) to evaluate the efficacy of BNC105 in renal cell carcinoma.

The Phase I clinical trial of BNC105 has been conducted in patients with advanced cancers at four Melbourne hospitals under the umbrella of Cancer Trials Australia. The objectives of the trial were to evaluate the safety, tolerability, and pharmacokinetics of BNC105 in cancer patients and to identify a dose level of BNC105 to be used in future clinical trials of BNC105. Following evaluation of the clinical trial information gathered to date a dose of 12.6 mg/m<sup>2</sup> has been selected for the next clinical trial of BNC105.

“This dose level was well tolerated by patients and rapidly achieved plasma drug levels required for VDA activity after a single intravenous dose” said Chief Executive Officer and Managing Director of Bionomics, Dr Deborah Rathjen. “In the Phase I trial, it was very encouraging to see a patient suffering from renal cell cancer who was treated at the 12.6 mg/m<sup>2</sup> dose level had stable disease for 9 weeks and we hope to further demonstrate efficacy in the Phase II trial”.

For the next stage of development of BNC105, Bionomics intends to utilize the expertise of HOG. to evaluate the efficacy of the compound in renal cell carcinoma. The HOG consists of a working association of over 400 dedicated community and research centre physicians and clinical research practitioners across the United States. It has successfully leveraged this network to conduct cancer clinical trials since its creation in 1984.

Dr. Nasser Hanna, Chairman of the HOG, said, “The Hoosier Oncology Group is enthusiastic to bring potentially innovative treatments to its members and patients, and Bionomics’ is a welcomed partner in that pursuit with its novel compound.”

Quake Pletcher, Executive Director of the HOG stated, “We welcome the opportunity to work with Bionomics in developing this novel VDA. The HOG has consulted with a number of leading genitourinary oncologists within its extensive network and there is a sense of excitement about the use of this agent for treating renal cancer.”

Renal cancer accounts for 2-3% of human malignancies and accounts for 85% of kidney cancers. Every year, approximately 200,000 cases are diagnosed worldwide, with 55,000 people diagnosed in the USA. The five year survival rate for patients with metastatic disease is less than 2%. Kidney cancer is asymptomatic, and in 40% of cases is diagnosed at an advanced stage.

“Bionomics is delighted to be working with an internationally highly regarded group such as the HOG as we progress the development of BNC105 for the treatment of renal cell cancer” said Dr Rathjen. “It provides the clinical reach to recruit suitable patients within a reasonable timeframe and the expertise to manage the type of multicentre trial that will be required.”

Dr Rathjen further commented “The success of Bionomics’ first clinical trial of BNC105 would not have been possible without the efforts of Cancer Trials Australia and the investigators and supporting staff at each of the clinical sites. We appreciate their tremendous support over the study. I also thank the patients for their participation in this trial.”

Details regarding the trial design for the renal cancer study will be the subject of a future statement. Additional Phase II clinical studies of BNC105 in other forms of cancer are also under consideration.

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

##### **Bionomics Limited**

Dr Deborah Rathjen  
CEO & Managing Director  
+618 8354 6101 / 0418 160 425  
[drathjen@bionomics.com.au](mailto:drathjen@bionomics.com.au)

##### **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)

##### **About Hoosier Oncology Group, Inc.**

The Hoosier Oncology Group operates as a cancer research organization established to evaluate innovative and promising methods and approaches to cancer treatment through, among other things, clinical research. Engendering cooperation between medical center scientists and community practitioners enables HOG to achieve the goal of treating cancer patients within their own communities, while contributing significant research to the worldwide battle against cancer.

For more information about HOG, visit [www.hoosieroncologygroup.org](http://www.hoosieroncologygroup.org)

##### **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, 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.*