Bionomics Limited (ASX: BNO; ADR: BMICY) has launched a Phase I/II clinical trial of its vascular disrupting agent BNC105 in women with ovarian cancer.

It is anticipated that up to 134 women will be enrolled at 18 sites across Australia, New Zealand and the United States, including sites in Indiana and Wisconsin.

The trial will evaluate BNC105 in combination with current standard therapies carboplatin and gemcitabine. The study will be 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.

Bionomics CEO and Managing Director Dr Deborah Rathjen said, “The design of this clinical trial is based on robust preclinical data demonstrating synergy between BNC105 and platinum-based therapies in improving survival rates of animals with solid tumours”.

“There is extremely promising data around this compound and we anticipate this trial will establish further potential of BNC105 in this new indication – to help women suffering ovarian cancer,” Dr Rathjen said.

Despite modest improvements in patient outcomes as a result of surgery or chemotherapy, the majority of ovarian cancer patients relapse and die of their disease. There is a clear unmet medical need for more effective systemic therapies.

Ovarian cancer is the fifth leading cause of cancer-related death among women. It is often diagnosed at an advanced stage after the cancer has spread beyond the ovary. In 2010 there were an estimated 21,880 new cases and 13,850 deaths from ovarian cancer in the US. It is estimated that approximately $2.2 billion is spent in the US each year on treating ovarian cancer.

In 2006 in Australia 1,226 ovarian cancer cases were diagnosed. The number of ovarian cancer cases in Australia increased by 47% between 1982 and 2006. It is anticipated that the number of new cases will continue to increase with an estimated 1,434 women expected to be diagnosed with ovarian cancer in 2015.

Drugs used to treat ovarian cancer had reported sales over US$2 billion in 2011.

Further details of this clinical trial in women with ovarian cancer can be found in the Clinical Appendix following this announcement.
As a Vascular Disruption Agent (VDA), BNC105 rapidly shuts down existing and new tumour blood vessels with no effect on normal blood vessels. Preclinical data has indicated that all solid tumour types, including breast, prostate and lung cancers, are susceptible to the VDA effect of BNC105 and that BNC105 also potently inhibits the growth of a broad range of cancer cells in culture.

In addition to the Phase I/II ovarian cancer trial, BNC105 is currently under evaluation, in combination with the mTOR inhibitor Everolimus (Afinitor), in a US multi-centre Phase II clinical trial in patients with metastatic renal cell carcinoma (RCC, a form of kidney cancer). Currently there are over 30 US-based clinical trial sites actively recruiting patients to participate in the trial. Results from the initial stage of the clinical trial demonstrated that the combination of BNC105 and Afinitor was safe and well tolerated, with several Phase I patients achieving at least disease stabilization. Five patients received at least 10 cycles of the combination. Enrolment in the RCC trial is due for completion at the end of the year.

The conduct of the RCC and ovarian clinical trials is aligned with Bionomics' Phase II partnership strategy for BNC105. Data from the RCC trial and the BNC105 clinical trial 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. The combination therapies used in Bionomics' clinical trials of BNC105 are used to treat many solid tumour types including breast, prostate, pancreatic, gastric and lung cancers as well as mesothelioma.

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**CLINICAL APPENDIX**

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<th>Name of Trial</th>
<th>Phase I/II BNC105P combination study in partially platinum sensitive ovarian cancer patients in first or second relapse</th>
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| Primary Endpoints | Phase I: To determine the Recommended dose of BNC105P given with gemcitabine and carboplatin.  
| | Phase II: To determine the Objective Response Rate (ORR) in those patients with evaluable disease (ORR = Complete Response (CR) or Partial Response (PR) according to RECIST 1.1 and/or GCIG CA125 criteria) |
| Secondary Endpoints | 1. Progression free survival (PFS) and overall survival (OS)  
| | 2. Adverse event (AE) rates (G2-5 AE, NCI CTCAE v4.0)  
| | 3. Effects on aspects of health related quality of life |
| Correlative Endpoints | 1. Effect of combining these drugs on the pharmacokinetics of BNC105P  
| | 2. Associations between baseline biomarkers, ORR, PFS, OS and AE |
| Study Design, Blinding Status | Single-arm Phase I (3-6 participants per dose level) followed by 2-arm randomised Phase II (1:1). Randomisation in Phase II is stratified by the presence or absence of measurable disease, 1st v 2nd relapse, progression free interval and site. Unblinded. |
| Product Development Status | Phase I/II |
| Treatment Method (route/frequency/dose levels) | Phase I: Carboplatin AUC 4 day 1, Gemcitabine escalations 800 and 1000mg/m2 days 1 and 8, BNC105P escalations at 12 or 16mg/m2 days 2 and 9, all q21 days for a maximum of 6 cycles, followed by single agent maintenance 16mg/m2 BNC105P for a maximum of 6 |
additional cycles.

Phase II: Carboplatin AUC 4 day 1, Gemcitabine 800 or 1000 mg/m2 days 1 and 8 with OR without BNC105P at previously defined MTD on days 2 and 9, all q 21 days for a maximum of 6 cycles, followed by a maximum of 6 cycles of single agent BNC105P 16mg/m2.

<table>
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<tr>
<th>Number of Trial Subjects</th>
<th>Phase I: maximum of 24 participants.</th>
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<td>Phase II: 110 participants (randomised 1:1) provides 71% power to detect an increase in the ORR from 20% (control) to 40% (experimental) with a 1-sided type 1 error rate of 5% allowing for 10 participants with missing data.</td>
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| Patient Population, Selection criteria | The target population for Phase I is women with ovarian cancer with a progression-free interval > 4 months after first or second line platinum based chemotherapy and for Phase II, women with ovarian cancer with 1st relapse from 4 to 9 months, or 2nd relapse from 4 to 12 months since the last dose of a platinum-based regimen. ECOG PS 0-1 for Phase I and 0-2 for Phase II. |

| Trial Location(s) | Australia, New Zealand, USA. |

| Trial Standard | ICH-GCP |

**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.


**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.