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ASX ANNOUNCEMENT
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BNC105 PHASE I/II TRIAL ACHIEVES A HIGH RESPONSE RATE IN OVARIAN CANCER

- **10 out of 15 patients with positive response in Phase I**
- **Recommended Phase II dose level of 12 mg/m^2 determined**
- **Results support continued development in the ovarian cancer setting**

Bionomics Limited (ASX:BNO, ADR:BMICY) has received positive results in the Phase I clinical trial of its cancer drug candidate BNC105 in women with ovarian cancer.

After completing the enrolment of 15 patients for the Phase I portion of the trial during 2013, data to date has found 10 of the patients have achieved a positive response according to the RECIST 1.1 and/or GCIG CA125 criteria.

The patients were treated with BNC105 in combination with the current standard therapy of carboplatin and gemcitabine. In line with the primary endpoint of the trial, 12mg/m^2 was identified as the recommended BNC105 dose to take into Phase II in this combination.

Biomarker analyses of blood samples from patients taken within four hours of administration of BNC105 demonstrated that the 12mg/m^2 dose induced a pharmacodynamic response indicative of BNC105 activity. The same biomarkers have been observed in association with BNC105 activity in previous clinical trials.

One patient has completed the protocol-prescribed 12 cycles of treatment comprised of six cycles of combination therapy and six cycles of BNC105 monotherapy. This patient has experienced clinical benefit and has continued on BNC105 monotherapy since.

12 of the 15 patients completed six cycles of combination therapy and commenced with BNC105 monotherapy. Thus far the mean number of treatment cycles across the study is 8.8, with each cycle of treatment representing three weeks. Three patients are currently continuing with treatment.

“This is very positive reinforcement of what we have come to expect for BNC105,” said CEO and Managing Director of Bionomics Dr Deborah Rathjen.

“Ovarian cancer is the fifth leading cause of cancer-related deaths in women and we are extremely grateful to the patients who participated in this study.”

“The market for drugs to treat ovarian cancer is valued at over $2 billion per annum and there remains significant unmet need for effective treatments. With these results we anticipate that we will be able advance our partnering strategy for BNC105.”

The trials are being conducted across six sites by the Australian and New Zealand Gynaecological Oncology Group (ANZGOG), the National Health and Medical Research Council Clinical Trials Centre (NH&MRC CTC) and the Hoosier Oncology Group in the United States.

“Some adverse effects were witnessed in patients but these were of haematological origin consistent with the backbone of the carboplatin and gemcitabine drug combination,” said Dr José Iglesias, Chief Medical Officer of Bionomics.

Principal Investigator for the trial Dr Danny Rischin commented “The results support continued development of BNC105 in the ovarian cancer setting to further investigate the potential of BNC105 as a new drug that may have a clinically significant impact.”

The American Cancer Society estimated that in 2013 approximately 22,240 new cases of ovarian cancer were diagnosed in the US and about 14,000 women would die of the disease.

Ovarian cancer is often diagnosed at an advanced stage after the cancer has spread beyond the ovary. Despite some improvements in patient outcomes the majority of patients relapse after surgery and chemotherapy and die of their disease. This clear unmet medical need is something Bionomics is endeavouring to address with BNC105.

Further details of the trial are given in the Clinical Appendix that accompanies this announcement.

FOR FURTHER INFORMATION PLEASE CONTACT:

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Clinical Appendix

Name of Trial	Phase I/II BNC105P combination study in partially platinum sensitive ovarian cancer patients in first or second relapse
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.
Number of Trial Subjects	Phase I: maximum of 24 participants. 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.
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 biopharmaceutical 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, memory loss and pain. Its oncology approach includes cancer stem cell therapeutics as well as vascular disruption in solid tumours. Bionomics partners include Merck & Co and Ironwood Pharmaceuticals.

Bionomics' discovery and development activities are driven by its four proprietary technology platforms: 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; 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); 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. Bionomics partners include Merck & Co and Ironwood Pharmaceuticals.

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 deals with Merck & Co and 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.

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