Bionomics Limited

ABN 53 075 582 740

ASX ANNOUNCEMENT
4 January 2019

COMMENCEMENT OF BNC105 CLINICAL TRIAL IN COMBINATION WITH NIVOLUMAB

- **The Australasian Gastro-Intestinal Trials Group (AGITG) is conducting a clinical trial with Bionomics' BNC105 in combination with nivolumab**
- **The trial will enrol patients with advanced metastatic colorectal cancer at approximately 15 sites around Australia**

Bionomics Limited (ASX:BNO, OTCQX:BNOEF), a global, clinical stage biopharmaceutical company, announces that an experimental phase II clinical trial of its cancer drug candidate, BNC105, in combination with Bristol-Myers Squibb's nivolumab, has commenced in patients with metastatic colorectal cancer, in an Australasian Gastro-Intestinal Trials Group (AGITG) sponsored trial supported by Bristol-Myers Squibb.

The MODULATE trial will investigate whether BNC105, a vascular disrupting agent, combined with an immune oncology drug, nivolumab, can be used to treat advanced colorectal cancer patients who have exhausted other treatment options. This will be the first clinical assessment of BNC105 in combination with an immunotherapy agent.

The Australasian Gastro-Intestinal Trials Group (www.gicancer.org.au) is conducting the MODULATE trial to evaluate new experimental approaches to immunotherapy treatment in colorectal cancer patients. Approximately 45 patients will receive BNC105 and PD-1 inhibitor nivolumab. A second group of approximately 45 patients will receive nivolumab in combination with a Signal Transduction Activator of Transcription (STAT3) inhibitor. The trial is open to recruitment at clinical oncology sites around Australia and the first patient first visit was conducted on 21 September.

Immunotherapy is a promising treatment for a number of cancers and uses the patient's own immune system to target and attack the cancer tumour. It works by stimulating lymphocytes, a type of white blood cell, which have infiltrated the tumour. The MODULATE trial aims to investigate whether BNC105 as a vascular disrupting agent that damages the tumour blood vessels leading to changes in the tumor microenvironment, will encourage lymphocytes to enter the tumour, and provide a new treatment option for patients with colorectal cancer. The administration of BNC105 with anti-PD-1 antibodies in mice bearing tumors comprising of colon adenocarcinoma cells has led to a synergistic reduction in tumour size.

Bionomics is pleased that this trial, evaluating the combination of BNC105 and the checkpoint inhibitor nivolumab, has been initiated. We are providing BNC105 for the trial for the benefit of colorectal cancer patients with advanced metastatic disease.

FOR FURTHER INFORMATION PLEASE CONTACT:

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About Bionomics Limited
Bionomics (ASX: BNO) is a global, clinical stage biopharmaceutical company leveraging its proprietary platform technologies to discover and develop a deep pipeline of best in class, novel drug candidates. Bionomics' lead drug candidate BNC210, currently in Phase 2 for the treatment of agitation in hospitalized elderly patients, is a novel, proprietary negative allosteric modulator of the alpha-7 (α7) nicotinic acetylcholine receptor. Bionomics has a strategic partnership with Merck & Co., Inc (known as MSD outside the United States and Canada).

www.bionomics.com.au

About BNC105
BNC105 is Bionomics' proprietary tubulin polymerization inhibitor that exerts direct anti-cancer activity by a number of different mechanisms. These mechanisms include starving the tumour through activation of acute tumour hypoxia following selective destruction of tumour blood vessels, induction of cancer cell death by upregulation of pro-apoptotic proteins, suppression of tumour growth by inhibiting cancer cell proliferation, modulation of the tumour microenvironment and amplification of the immune response to fight cancer, in synergy with checkpoint inhibitors.

About nivolumab
Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. www.bmsa.com.au. Nivolumab is a programmed death-1 (PD-1) immune checkpoint inhibitor that is designed to uniquely harness the body's own immune system to help restore anti-tumour immune response. In July 2014, nivolumab was the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world.

In Australia, nivolumab is approved by the Therapeutic Goods Administration (TGA) for treatment of eleven indications across seven distinct cancer types – advanced melanoma, advanced lung cancer, advanced renal cell carcinoma, advanced bladder cancer, advanced liver cancer, advanced head and neck cancer and relapsed/refractory classical Hodgkin lymphoma. www.tga.gov.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 announcement that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' drug candidates (including BNC210, BNC101 and BNC105), its licensing agreements with Bristol-Myers Squibb and any milestone or royalty payments thereunder, drug discovery programs, ongoing and future clinical trials, and timing of the receipt of clinical data for our drug candidates 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 unexpected safety or efficacy data, unexpected side effects observed in clinical trials, risks related to our available funds or existing funding arrangements, our failure to introduce new drug candidates or platform technologies or obtain regulatory approvals in a timely manner or at all, regulatory changes, inability to protect our intellectual property, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantage, as well as other factors. Results of studies performed on our drug candidates and competitors' drugs and drug candidates may vary from those reported when tested in different settings.

Clinical Appendix

Study Title:

Modulation of the tumour microenvironment using either vascular disrupting agents or STAT3 inhibition in order to synergise with PD1 inhibition in microsatellite stable, refractory colorectal cancer (MODULATE)

Study Number:

Protocol Number CA209-99U

Study Design:

Approximately 90 microsatellite stable refractory colorectal cancer patients randomized 1:1 to Arm (1) nivolumab + BNC105, or Arm (2) nivolumab + a STAT3 inhibitor. Patients remain on study for 24 months or until disease progression or unacceptable toxicity.

Primary Objective:

- To determine the objective response rates of the combination of nivolumab and BNC105 and the combination of nivolumab and a STAT3 inhibitor

Secondary Objectives:

- To determine progression free survival
- To evaluate the adverse event profile of the drug combinations
- To determine overall survival

Exploratory Objective:

- To evaluate selected biomarkers related to immunomodulation and inflammation