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ASX ANNOUNCEMENT
31 October 2017

BNC101 Phase 1 Clinical Trial Recruitment Completed

- **Positive pharmacodynamic data including supporting evidence of target engagement**
- **Gene expression changes correlated with level of LGR5 expression**
- **Data support out-licensing process**

Bionomics Limited (ASX:BNO, OTCQX:BNOEF), a biopharmaceutical company focused on the discovery and development of innovative therapeutics for the treatment of diseases of the central nervous system (CNS) and cancer, is pleased to announce its BNC101 Phase 1 clinical trial in patients with metastatic colon cancer is now fully recruited and initial pharmacodynamic marker data are available.

BNC101 is an anti-LGR5 humanised monoclonal antibody being developed to treat solid cancers. It aims to prevent or delay tumour recurrence by targeting LRG5, a cancer stem cell (CSC) marker that is over-expressed in metastatic colorectal cancers and other solid tumour types. LGR5 is also thought to regulate cancer cell adhesion.

The recommended Phase 2 dose level of 15 mg/kg has been confirmed.

In addition, target engagement has been demonstrated in patient tumour biopsy material using Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) with further supporting evidence from Magnetic Assisted Laser Desorption Ionisation-Imaging Spectrometry (MALDI-IMS). LC/MS/MS and MALDI-IMS enabled the co-localisation of BNC101 antibody with LGR5 protein to be detected.

With no dose limiting toxicities or other significant safety issues, the Phase 1 clinical trial also provided first evidence confirming the mechanism of action of LGR5, the target for BNC101, in colon cancer patients through evaluation of gene expression in tumour biopsies.

Gene expression changes identified through ribonucleic acid (RNA) sequencing were observed within LGR5 modulated Wnt signalling and cell adhesion pathway panels and in immuno-oncology associated gene groups, relevant to the mechanism of action of BNC101.

These gene expression changes have been correlated with the level of LGR5 expression in patient biopsies. LGR5 expression was measured by the quantification of messenger ribonucleic acid (mRNA) expression in patient biopsies using in-situ hybridisation.

Colorectal cancer is the second most prevalent cancer type, yet overall survival is significantly behind other high occurrence cancers. In metastatic colorectal cancer, five-year survival is just 12%, with current treatment options offering minimal therapeutic benefit to the patient population.

Bionomics' CEO and Managing Director, Dr Deborah Rathjen commented, "We are very pleased that the recommended dose level of 15 mg/kg has been confirmed and that BNC101 continues to be safe and well tolerated. The combined data showing that BNC101 co-localised with LGR5 and induced gene expression changes in patient tumours support target engagement. We anticipate that this data and further pharmacodynamic data from the clinical trial will be highly supportive of our ongoing out-licensing effort".

"With overall survival rates of metastatic colorectal cancer being so low, we believe that BNC101 has the potential to offer real therapeutic benefit to patients where there has previously been limited treatment options. We thank the clinicians, patients and their families for their involvement in this clinical trial", Dr Rathjen added.

Emerging data demonstrate that cancer stem cells can also generate an environment in the tumour that suppresses the immune system from functioning as it normally would to attack tumour cells.

In April 2017, Bionomics presented new pre-clinical data of BNC101 at the American Association for Cancer Research (AACR) conference in Washington, DC. The data showed in mouse models of colon cancer that treatment with BNC101 and a checkpoint inhibitor has a greater reduction in T regulatory cells. T regulatory cells are an immune suppressive cell. In addition, when BNC101 was administered in combination with the checkpoint inhibitor, an increase in tumour attacking cytotoxic T cells was observed compared to treatment with the checkpoint inhibitor alone.

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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 focused on the treatment of serious central nervous system disorders and on the treatment of cancer. Bionomics' lead drug candidate BNC210, currently in Phase 2 for the treatment of generalized anxiety disorder and for post-traumatic stress disorder, is a novel, proprietary negative allosteric modulator of the alpha-7 (α7) nicotinic acetylcholine receptor. The Company is also developing BNC101, its lead humanised monoclonal antibody targeting a key receptor on cancer stem cells that is overexpressed in metastatic colorectal cancer, metastatic pancreatic cancer and many other solid tumours; BNC101 entered clinical trials in the first quarter of 2016. Bionomics has a strategic partnership with Merck & Co., Inc (known as MSD outside the United States and Canada).

www.bionomics.com.au

Factors Affecting Future Performance
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"believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements.

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