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**ASX ANNOUNCEMENT**  
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## **SUCCESSFUL FDA SUBMISSION PAVES WAY FOR CLINICAL TRIAL OF CANCER STEM CELL DRUG CANDIDATE**

Bionomics Limited (ASX:BNO, ADR:BMICY), 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, today announced that its BNC101 investigational new drug application (IND) submission to the US Food and Drug Administration has been accepted.

Bionomics plans to initiate a Phase 1 clinical trial in patients with metastatic colon cancer and in patients with metastatic pancreatic cancer prior to 31 December 2015.

Bionomics' CEO & Managing Director Dr Deborah Rathjen said "This is a significant milestone for the Company. BNC101 is a new class of anti-cancer agent which targets cancer stem cells. Many current drugs do not specifically target cancer stem cells. We believe that drugs, such as BNC101, specifically targeting cancer stem cells will reduce the risk of cancer recurrence and metastasis and have the potential to lead to better patient outcomes."

BNC101 is a first-in-class, high affinity anti-LGR5 humanized monoclonal antibody targeting cancer stem cells. LGR5 is a receptor overexpressed in metastatic colorectal cancer, metastatic pancreatic cancer and many other solid tumours.

Dr José Iglesias, Bionomics' Chief Medical Officer said, "BNC101 was discovered by Bionomics using our CSCRx platform and it is immensely satisfying to see it move to this next stage of development. We are very encouraged by the results of our preclinical studies of BNC101 which have demonstrated efficacy in models of colon, pancreatic, breast and small cell lung cancer".

BNC101 is designed to prevent or delay tumour recurrence, and reduce cancer stem cells as a single agent and in combination with standard chemotherapy treatment. Furthermore, in preclinical studies, BNC101 reduced circulating tumour cells that express LGR5.

In IND-enabling preclinical studies BNC101 was well tolerated at doses up to 150 mg/kg in a 28-day repeat dose study.

The Phase 1 trial will aim to demonstrate that BNC101 is safe and well tolerated as well as that it is able to delay disease relapse in treated patients. Initial indications will be metastatic colorectal cancer and metastatic pancreatic cancer. Development will occur initially as a combination therapy with standard of care chemotherapies while long term development strategies will evaluate

BNC101 in monotherapy to prevent or delay tumour relapse. Further details will be provided upon commencement of the clinical trial.

The global market for metastatic colorectal cancer treatments has been predicted to grow to US\$9.4 billion by 2020. In 2015, the U.S. Center for Disease Control and Prevention, or CDC, estimates that there will be approximately 133,000 new cases of metastatic colorectal cancer in the United States. Currently, the five-year survival rate for metastatic colorectal cancer patients is approximately 11% with a median overall survival span for metastatic colorectal cancer ranging from approximately 20 to 30 months. LGR5 expression has been correlated with poor patient response or survival in metastatic colorectal cancer patients.

The global metastatic pancreatic cancer drug market is estimated to be US\$1.2 billion in 2015. In 2015, the CDC estimates that there will be approximately 49,000 new cases of metastatic pancreatic cancer in the United States. For pancreatic cancer patients overall, the five-year survival rate is approximately 7% for all stages combined and only 2% for patients with metastatic pancreatic cancer, according to the U.S. National Cancer Institute. Studies have found that the median overall survival span for metastatic pancreatic cancer patients ranges from approximately eight to 11 months. Although there are a number of approved drugs for the treatment of metastatic pancreatic cancer, there continues to be a significant unmet medical need.

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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, is a novel, proprietary negative allosteric modulator of the alpha-7 ( $\alpha 7$ ) nicotinic acetylcholine receptor. The Company is also developing BNC101 its lead humanized 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 is expected to enter clinical trials in the fourth quarter of 2015. Bionomics has strategic partnerships with Merck & Co. in pain and cognition.

[www.bionomics.com.au](http://www.bionomics.com.au)

#### **Factors Affecting Future Performance**

This presentation 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' drug candidates (including BNC210 and BNC101), its licensing agreements with Merck & Co. 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.

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