ABN 53 075 582 740

ASX ANNOUNCEMENT
4 April 2016

BIONOMICS INITIATES PHASE 1 STUDY OF BNC101 FOR TREATMENT OF METASTATIC COLORECTAL CANCER

ADELAIDE, Australia, 4 April 2016: 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, today announced it had initiated a Phase I clinical study for its anti-cancer stem cell drug candidate known as BNC101.

The move follows acceptance of an investigational new drug (IND) application by the US Food & Drug Administration (FDA) in August 2015. Pre-clinical studies to support the IND application showed that BNC101 was well tolerated with no adverse dose identified.

Bionomics Chief Executive Officer and Managing Director Dr Deborah Rathjen said, "This is an important milestone for the business as we continue to build on our proven strengths and capabilities as a drug discoverer and early stage developer of important new therapies with significant clinical and commercial potential."

“It is another step forward as we build a globally competitive Australian business with integrated drug discovery and development expertise to support strategic partnerships and clinical development of multiple promising drug candidates.”

The open label, multi-centre clinical trial in patients with metastatic colorectal cancer will aim to demonstrate that BNC101 is safe and well tolerated and that it is able to delay disease relapse in treated patients. The trial will be conducted at specialist centres across Australia and will run in two parts, firstly with BNC101 alone and then in combination with standard of care chemotherapy. Each part has two phases, an escalation to find the optimal dose level and then an expansion of the study at that dose level. The Principal Investigator is Dr Jayesh Desai, Medical Oncologist at the Royal Melbourne Hospital.

The clinical trial appendix follows this announcement.

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BNC101
BNC101 is a first-in-class, high affinity anti-LGR5 humanized monoclonal antibody targeting cancer stem cells. LGR5 is a receptor over-expressed in metastatic colorectal 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 treatments. Preclinical studies showed BNC101 reduced circulating tumour cells that express LGR5. Studies to support IND approval showed BNC101 was well tolerated and an adverse dose was not identified.

Metastatic colorectal cancer
In 2015 the US Centers for Disease Control and Prevention (CDC) estimated there were approximately 133,000 new cases of metastatic colorectal cancer in the United States.

The current five-year survival rate for metastatic colorectal cancer patients is approximately 11 per cent with a median overall survival span for metastatic colorectal cancer ranging from approximately 20 to 30 months. The global market for metastatic colorectal cancer treatments is estimated to grow to US$9.4 billion by 2020.

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 (α7) 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 first quarter of 2016. Bionomics has strategic partnerships with Merck & Co., Inc (known as MSD outside the United States and Canada) in pain and cognition.
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 announcement 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.

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 announcement.

Clinical Appendix

Name of finished product:

BNC101

Study Title:

A Phase I, Dose Escalation Study of BNC101 (anti-LGR5 humanized monoclonal antibody) in patients with metastatic colorectal cancer

Study Number:

BNC101.001

Clinical Phase:

Phase I

Rationale:

BNC101 is a highly-specific monoclonal antibody to LGR5 and will target cancer stem cells by blocking key stem cell survival signals downstream of LGR5. The clinical strategy is to use BNC101 in combination with standard-of-care chemotherapy to inhibit cancer stem cell activity and/or directly eliminate cancer stem cells. As a result, BNC101 is proposed to significantly increase the duration of response and survival compared to current standard-of-care therapies for colorectal cancer.

Study Design:

Phase I, open label, multicenter study

Standard 3 + 3 dose escalation to determine the maximum tolerated dose (MTD) followed by expansion of the patient pool at that MTD.

Primary Objective:

To determine the MTD of BNC101, both as single agent and in combination chemotherapy in metastatic colorectal cancer patients.

Secondary Objectives:

- To determine the RP2D of BNC101, both as single agent and in combination chemotherapy in metastatic colorectal cancer patients.
- To evaluate the safety and tolerability of BNC101 [adverse events (AEs), dose omissions or delays]
- To assess for immunogenicity of BNC101 (production of antibodies against BNC101)
- To determine the pharmacokinetics (PK) of BNC101 (half-life, volume of distribution and clearance), both as single agent and in combination with chemotherapy
- To make a preliminary assessment of the Overall Response Rate (ORR), Progression-Free Survival (PFS) and Overall Survival (OS) of metastatic colorectal cancer patients treated with BNC101

Exploratory Objectives:

- To assess changes in disease-related biomarkers (CEA)
- To evaluate biomarkers of activity [pharmacodynamics, e.g. circulating tumour cells (CTCs), LGR5+ cells, circulating tumour DNA]

Number of subjects:

Approx 50-60

Subjects will be recruited at clinical research centres in Australia.

Dosing and Schedule:

The schedule of administration will be weekly over a 4 week schedule.

Escalation will take place in two separate sets of cohorts, in a staggered fashion: single agent BNC101 dose escalation will precede dose escalation in the combination chemotherapy cohorts. In the latter, BNC101 will be dose-escalated in combination with FOLFIRI.