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New BNC105 Clinical Trial in Combination with Keytruda

- Collaboration between Peter MacCallum Cancer Centre and Olivia Newton-John Cancer Wellness & Research Centre (ONJ Centre) receives \$2.25m grant to fund BNC105 trial in combination with Keytruda, a checkpoint inhibitor developed by MSD
- The trial will enroll patients with advanced melanoma who are unresponsive to standard treatments
- Trial anticipated to commence 1H, 2017 CY

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, advises that its cancer drug candidate BNC105 will be evaluated in a combination trial with blockbuster immune-oncology drug Keytruda.

Grant funds to enable the trial have been awarded by the Victorian Government through the Victorian Cancer Agency to the Peter MacCallum Cancer Centre. Keytruda will be provided by Merck & Co., Inc (known as MSD outside the United States and Canada).

This will be the first clinical assessment of the combination of the PD-1-inhibitor Pembrolizumab (Keytruda) with the vascular disrupting agent BNC105. It will be tested in patients with advanced cases of melanoma, who were unresponsive to standard treatments.

Professor Jonathan Cebon, a leading Australian oncologist in immune therapies for cancer and Medical Director of the ONJ Centre, has collaborated with Bionomics to identify a novel strategy to improve the immunogenicity of cancer – the combination of anti-PD-1 with BNC105. He will lead the trial in collaboration with Professor Grant McArthur of the Peter MacCallum Cancer Centre, Jointly they have taken the lead in clinical trials of checkpoint inhibitors in patients with melanoma. The trial will also involve other Victorian investigators and hospitals.

Professor Jonathan Cebon said "We are delighted to receive support for this three way collaboration between our two leading cancer Centres and Bionomics.

"I am delighted to be collaborating with an Australian based global biotechnology company on such an important opportunity in immune therapies for cancer," commented Professor Grant McArthur.

"We are now poised to significantly impact melanoma through remarkable advances in systemic therapy that target the oncogenic drivers of melanoma and/or activate the host immune response by inactivating key immune checkpoints to activate T-cell mediated killing. These advances have led to the median survival of patients with advanced disease being extended from a historical nine months to over two years," said Dr Deborah Rathjen, Bionomics' CEO and Managing Director.

"We have maintained a firm belief that BNC105 has potential to reach the vanguard of cancer treatments. This funding and the strong interest and determination of the highly respected Peter MacCallum Cancer Centre demonstrate that BNC105 may well advance as an important combination treatment."

Melanoma is the fourth most common cancer in Australia. Almost 1800 Australians die every year from melanoma. The impact of melanoma in young people is profound being the most common cancer in 20-40 year olds. Unlike other cancers there has been no reduction in standardised mortality over the last two decades.

Details of the Clinical Trial

The Victorian Cancer Agency Translational Research Project will target the problem of treatment resistance in advanced melanoma. Since no single approach is used to treat melanoma this translational research project will tackle three of the most important issues in the resistance to systemic therapy of patients with metastatic melanoma by performing entirely novel early phase clinical trials including the BNC105 trial to establish safety, biological and preliminary efficacy data to address:

- 1. Preventing resistance to combined BRAF & MEK inhibition
- 2. Extending the benefit of anti-PD-1 based therapies to higher proportions of patients
- 3. Improving the efficacy of immune checkpoint inhibitors in melanoma brain metastases.

Results from the trial are anticipated to include objective response rate of the combination in overcoming therapeutic resistance in melanoma, overall survival, progression-free survival, duration of response to pembrolizumab and BNC105, the effect of pembrolizumab and BNC105 on the tumour micro-environment, and baseline genomic and immunological predictors of the outcomes.

The study will have a dose escalation cohort and expansion cohorts at the recommended Phase 2 dose. Pembrolizumab will be combined with BNC105 in 28 day cycles with dose escalation in a 3+3 design. An expansion cohort of 20 patients with a minimum of 8 patients required to have paired biopsies at baseline and 10-17 days after commencing study therapy.

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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 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 entered 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

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 and amplification of the immune response to fight cancer, in synergy with checkpoint inhibitors.

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.