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ASX ANNOUNCEMENT 20 January 2021

# TREATMENT OF COLORECTAL CANCER PATIENTS IN PHASE 2 BNC105 / NIVOLUMAB COMBINATION CLINICAL TRIAL COMPLETED – TOPLINE DATA IN 2Q 2021

Bionomics Limited (ASX: BNO, OTCQB:BNOEF), a global, clinical stage biopharmaceutical company, today announced that all patients have completed their treatment phase in the MODULATE clinical trial, an experimental Phase 2 trial of BNC105 in combination with Bristol Myers Squibb's nivolumab (OPDIVO®) in patients with metastatic colorectal cancer. The trial Sponsor, the Australasian Gastro-Intestinal Trials Group (AGITG), is expecting that results will be ready in Q2 2021 which is ahead of the previously announced timeline for topline data of early 2023.

The AGITG (www.gicancer.org.au) is conducting the MODULATE trial to evaluate new experimental approaches to immunotherapy treatment in colorectal cancer patients. In one arm of the trial, it is investigating whether Bionomics' BNC105, a vascular disrupting agent, combined with nivolumab, a PD-1 (programmed death-1) immune checkpoint inhibitor, can be used to treat advanced colorectal cancer patients who have exhausted other treatment options. A second group of patients are receiving nivolumab in combination with a Signal Transduction Activator of Transcription (STAT3) inhibitor.

Dr. Errol De Souza, Executive Chairman of Bionomics said, "We thank AGITG, the trial Sponsor, and the patients who participated in the study, and look forward to reporting the topline data in Q2 2021".

**AUTHORISED BY: DR ERROL DE SOUZA, EXECUTIVE CHAIRMAN** 

## FOR FURTHER INFORMATION PLEASE CONTACT:

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### **About Bionomics Limited**

Bionomics (ASX: BNO, OTCQB:BNOEF) 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 development for initiation of a second Phase 2 trial for the treatment of PTSD, is a novel, proprietary negative allosteric modulator of the alpha-7 (α7) nicotinic acetylcholine receptor. Beyond BNC210, Bionomics has a strategic partnership with Merck & Co., Inc (known as MSD outside the United States and Canada).

### www.bionomics.com.au

# **About Bristol Myers Squibb**

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. For more information about Bristol Myers Squibb, visit us at https://www.bms.com/au.

# **Bristol Myers Squibb: Advancing Oncology Research**

At Bristol Myers Squibb, patients are at the centre of everything we do. The focus of our research is to increase quality, long-term survival for patients and make cure a possibility. Through a unique multidisciplinary approach powered by translational science, we harness our deep scientific experience in oncology and Immuno-Oncology (I-O) research to identify novel treatments tailored to individual patient needs. Our researchers are developing a diverse, purposefully built pipeline designed to target different immune system pathways and address the complex and specific interactions between the tumor, its microenvironment and the immune system. We source innovation internally, and in collaboration with academia, government, advocacy groups and biotechnology companies, to help make the promise of transformational medicines, like I-O, a reality for patients.

# **About Immuno-Oncology (I-O)**

Immuno-oncology is based on the premise that the immune system could be a powerful and effective tool for recognising and fighting disease. Immuno-oncology treatments are designed to harness the patient's own immune system to combat cancer by targeting the same immune pathways that tumour cells use to evade recognition and destruction.

OPDIVO® has been approved by the Therapeutic Goods Administration (TGA) for the treatment of a range of cancers including lung, head and neck, kidney, bladder and liver cancer.

### **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), 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.