Bionomics Announces Publication of Positive Phase 2a Data for BNC210 in Generalized Anxiety Disorder Patients

Bionomics Limited (ASX: BNO, OTCQB:BNOEF), a global, clinical stage biopharmaceutical company, today announced the online publication of their paper entitled Cholinergic Modulation of Disorder-Relevant Neural Circuits in Generalized Anxiety Disorder in the peer-reviewed journal Biological Psychiatry. This paper describes the results of a placebo-controlled functional magnetic resonance imaging (fMRI) study conducted at the Institute of Psychiatry, Psychology and Neuroscience (IOPPN) at King’s College London (KCL) which evaluated the effects of BNC210 treatment on brain responses to images of “fearful faces” in 24 Generalized Anxiety Disorder (GAD) patients.

BNC210, Bionomics’ proprietary compound, is a novel, negative allosteric modulator (NAM) of the alpha 7 nicotinic acetylcholine receptor (α7 nAChR) in development for the treatment of anxiety and stressor-related disorders. Lorazepam, a commonly used treatment for anxiety, was used as a positive control in the study. fMRI studies have previously shown that GAD is associated with hyperactivity and connectivity in the amygdala-anterior cingulate cortex networks in the brain, and the normalization of this irregular activity is thought to be critical for successful anxiety treatment.

Treatment with BNC210 significantly reduced amygdala reactivity to fearful faces relative to placebo and, similar to lorazepam, reduced connectivity between the amygdala and the anterior cingulate cortex network. These data demonstrate for the first time that the aberrant function of anxiety disorder-relevant neural circuits can be beneficially altered by BNC210 and support the potential for cholinergic modulation as a novel target for anxiolytic pharmacotherapy.

BNC210 was safe and well tolerated in the GAD subjects. “This unique safety profile separates BNC210 from current anxiety therapies like lorazepam, which have the potential for sedation and addictive liability-related side effects. This study showed that acute doses of BNC210 performed equally as well as lorazepam on the reduction of amygdala hyperactivity and offers hope of new anxiety treatments being developed” said Principal Investigator, Professor Allan H Young, Director, Centre for Affective Disorders, IOPPN, at KCL. “These data provide evidence that BNC210 may have the potential to make a real clinical difference for patients with anxiety.”

Professor Steven Williams, Head of Neuroimaging Department and Professor of Imaging Sciences at KCL added: “The selective modulation of the brain’s limbic system by BNC210 supports the case for further investigation in conditions ranging from anxiety to mood disorders and Post-Traumatic Stress Disorder (PTSD)”.

“Bionomics is preparing for a Phase 2b trial with BNC210 in PTSD patients. The demonstration of anti-anxiety potential of BNC210 in GAD patients supports our investigations into PTSD patients who experience anxiety as one of their four symptom clusters and exhibit similar fMRI changes in neural
activity and connectivity as seen in GAD patients” said Dr. Errol De Souza, Executive Chairman of Bionomics.

About Biological Psychiatry

_Biological Psychiatry_ is the official journal of the Society of Biological Psychiatry and is one of the most selective and highly cited journals (ranked 1st in Psychiatry by citations) in the field of psychiatric neuroscience with an acceptance rate of less than 10%.

The online publication can be found by copying the following into a web browser: https://reader.elsevier.com/reader/sd/pii/S0006322319319377?token=B6312820E4DFAC253DC557E48854F9303C2DA480514E6ABE2A954D7B9A2FF1E34071AE20C018DA9DAC9F7BB375C8EF3B

About Anxiety Disorders

Anxiety is the most common mental health condition in Australia. On average, one in three women and one in five men will experience anxiety at some stage in their life. Anxiety disorders are also the most common mental illness in the U.S., affecting 40 million adults age 18 and older, or 18.1% of the population every year.

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

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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. Bionomics’ lead drug candidate BNC210 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) and a pipeline of pre-clinical ion channel programs targeting pain, depression, cognition and epilepsy.


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.