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# ASX ANNOUNCEMENT 3 April 2020

# Publication of Positive Phase 2a Data for BNC210 in Generalized Anxiety Disorder Patients – Additional Information

Bionomics Limited (ASX: BNO, OTCQB:BNOEF), a global, clinical stage biopharmaceutical company, provides the following additional information from the publication of positive Phase 2a Data for BNC210 in Generalized Anxiety Disorder that was announced yesterday.

The table below is a summary of the statistical significance of BNC210 treatment on (1) amygdala hyperactivity and (2) functional connectivity between the amygdala and the anterior cingulate cortex in subjects with Generalized Anxiety Disorder (GAD) while viewing fearful faces during functional magnetic resonance imaging.

|    | BNC210 300 mg  | Left<br>Amygdala | Right<br>Amygdala | Paper<br>Reference* |
|----|--|------------------|-------------------|---------------------|
| 1. | Anxious subjects viewing Fearful Faces during fMRI,<br>experienced significant amygdala activation as<br>expected.   | p=0.001          | p=0.001           |                     |
| 2. | Anxious subjects treated with BNC210 showed significant reduction of this amygdala activation.   | p=0.011          | p=0.006           | Figure 2,           |
| 3. | The positive control for the study, the<br>benzodiazepine lorazepam (1.5 mg), significantly<br>reduced left amygdala activation and reduced<br>activation in the right amygdala but did not reach<br>significance. | p=0.047          | p=0.09 (NS)       | Page 5              |
| 4. | BNC210 treatment significantly reduced functional connectivity between the left and right amygdala and the anterior cingulate cortex.  | P=0.012          |                   | Figure 3,<br>Page 6 |

\*A higher dose of BNC210 was also used in the study but did not achieve statistically significant reduction of amygdala hyperactivity compared to placebo.

\*\*Wise T<sup>1</sup>, Patrick F<sup>2</sup>, Meyer N<sup>3</sup>, <u>Mazibuko N</u><sup>4</sup>, Oates AE<sup>5</sup>, van der Bijl AHM<sup>6</sup>, Danjou P<sup>7</sup>, O'Connor SM<sup>8</sup>, <u>Doolin E<sup>8</sup></u>, <u>Wooldridge C<sup>4</sup></u>, <u>Rathjen D<sup>9</sup></u>, <u>Macare C<sup>10</sup></u>, <u>Williams SCR<sup>11</sup></u>, <u>Perkins A<sup>12</sup></u>, <u>Young AH<sup>12</sup></u>. (2020). Cholinergic Modulation of Disorder-Relevant Neural Circuits in Generalised Anxiety Disorder. In press, Biological Psychiatry 2020.

### Null Hypothesis, p-Values and Statistical Significance

<u>The null hypothesis</u> is usually an hypothesis of "no difference" e.g. there <u>is no</u> difference in amygdala hyperactivity in anxious subjects administered drug versus those administered placebo.

A null hypothesis is proposed for each study before it begins.

In statistics, <u>the *p*-value is the probability</u> of obtaining the observed results, using a statistical hypothesis test, assuming that the null hypothesis is correct.

When the p value is less than 0.05 ( $p \le 0.05$ ) it is referred to as statistically significant because it indicates strong evidence against the null hypothesis i.e. there is a less than 5% probability that the null hypothesis is correct.

Therefore, the null hypothesis is rejected, and the alternative hypothesis is accepted i.e., there <u>is</u> a difference in amygdala hyperactivity in anxious subjects administered drug versus those administered placebo.

## **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=B6312820E4DFAC253DC557E48 854F9303C2DA480514E6ABE2A954D7B9A2FF1E34071AE20C018DA9DAC9F7BB375C8EF3B

## **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.

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# FOR FURTHER INFORMATION PLEASE CONTACT:

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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 ( $\alpha$ 7) 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.

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), 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.