

ABN 53 075 582 740

ASX ANNOUNCEMENT 16 May 2019

# Bionomics Present Results of the PTSD Trial and Exposure-Response Analyses at the 74<sup>th</sup> Society of Biological Psychiatry (SOBP) Annual Scientific Conference.

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), will present expanded data from the Phase 2 Post Traumatic Stress Disorder (PTSD) Clinical Trial using BNC210.

The data will be presented by Dr Susan O'Connor, VP Strategic Initiatives and Innovation and Ms. Elizabeth Doolin, VP Clinical Development from Bionomics and is co-authored by scientists from Bionomics and Pharmetheus Pharmacokinetic Consulting Services, Uppsala Sweden.

The presentation includes additional information leading to the following conclusions:

- 1. Pharmacometric (PK) modelling showed that exposure from the BNC210 liquid suspension formulation was insufficient to achieve efficacy in the PTSD Trial [600 mg b.i.d, mean AUC at steady state was 14.3 mg.hr/L (SD 5.4)].
- 2. Exposure-response modelling indicated the potential for BNC210 in the treatment of PTSD symptoms provided that adequate blood levels are achieved (~25 mg.hr/L).
- 3. These analyses justify further evaluation of BNC210 in PTSD patients and provide a basis for optimal design of future trials to demonstrate efficacy.

The presentation poster also includes encouraging data on the improved solid dose formulation of BNC210 which has the potential to overcome the food effect of the suspension formulation and is intended for use in future trials.

The goal for this solid dose is to achieve steady state concentrations of ~25 mg.hr/L which, based on the PK-PD analysis, will increase the likelihood of statistically significant reduction in CAPS-5 scores with BNC210 treatment compared to placebo, and thus may reach the primary end-point in the next PTSD trial.

The SOPB meeting is being held 16 – 18 May 2019, at the Hilton Chicago, Chicago, Illinois. This is annual event occurring just before or after the American Psychiatric Association Meeting and presents an opportunity for scientists and psychiatrists to attend both conferences. The theme this year; "Innovations in Clinical Neuroscience: Tools, Techniques and Transformative Frameworks" is particularly appropriate for showcasing the BNC210 Exposure-Response modelling data.

The poster will be available on the Company's website at the conclusion of the presentation.

## **Poster Details**

Poster T255: The Therapeutic Potential of BNC210 for the Treatment of PTSD is Informed by

Pharmacometric Analyses.

Date: Thursday,16 May 2019

Time: 5:00 PM – 7:00 PM Salon D

Location: Chicago, III.

# 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, currently in Phase 2 for the treatment of agitation, 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.