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ASX ANNOUNCEMENT
19 September 2019

Bionomics Submits an Application for FDA Fast Track Designation for BNC210 for the Treatment of PTSD

- **Positive FDA feedback at the Type C meeting to discuss BNC210 for the treatment of PTSD**
- **A request for Fast Track designation for BNC210 has been submitted to the FDA**

Bionomics Limited (ASX:BNO, OTCQX:BNOEF), a global, clinical stage biopharmaceutical company leveraging proprietary platform technologies to discover and develop a deep pipeline of novel drug candidates targeting ion channels, is pleased to announce positive feedback from the FDA at the recent Type C meeting to discuss BNC210 for the treatment of Post-Traumatic Stress Disorder (PTSD). The objective of the meeting was to seek guidance on the plans for further development of BNC210 in a second Phase 2 trial in PTSD patients using the newly developed tablet formulation and aiming for the exposure levels predicted from the pharmacometric analyses to have potential for clinical benefit. The FDA was supportive of the approaches outlined by Bionomics.

Furthermore, following discussions with the FDA, Bionomics has submitted an application for Fast Track designation for BNC210 for the treatment of PTSD. Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The application outlines the non-clinical and clinical data for BNC210 showing efficacy in animal models representing symptoms of PTSD, such as anxiety, hyperarousal and fear extinction, and an improved clinical and non-clinical safety and tolerability profile compared to the standard of care therapies for PTSD which are the SSRIs, sertraline and paroxetine.

At the same time, Bionomics is completing a single ascending dose pharmacokinetic study in healthy volunteers to demonstrate that blood levels of BNC210, predicted to be necessary to meet the primary efficacy endpoints in any further trials in PTSD patients, are achievable using the new solid dose formulation. The results of this trial are expected in October 2019.

FOR FURTHER INFORMATION PLEASE CONTACT:

Dr Errol De Souza
Executive Chairman
BIONOMICS LIMITED
Ph: +61 8 8354 6100

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.

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.