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ASX ANNOUNCEMENT
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Bionomics Announces Fast Track Designation Granted by U.S. FDA to BNC210 Development Program for the Treatment of PTSD

Bionomics Limited (ASX:BNO, OTCQX:BNOEF), a global, clinical stage biopharmaceutical company discovering and developing a pipeline of novel drug candidates targeting ion channels, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the BNC210 development program for the treatment of Post-Traumatic Stress Disorder (PTSD) and other trauma-related and stressor-related disorders.

Bionomics is currently developing a novel solid dose formulation of BNC210 which has recently been shown to achieve the blood levels predicted as necessary to meet the clinical trial primary endpoint for effectiveness for treating PTSD patients; preparations are underway for optimization of the solid dose formulation in anticipation of initiation of a Phase 2b trial in PTSD patients.

“FDA’s decision to grant Fast Track designation is an important recognition of the high unmet medical need in PTSD and potential benefits of BNC210 with a novel mechanism of action in the treatment of this disorder,” said Dr. Errol De Souza, Executive Chairman of Bionomics. “We are pleased with the progress that we have made over the last year in getting BNC210 back on track by carrying out extensive pharmacometric analysis and two pharmacokinetic studies demonstrating that the target blood levels predictive of efficacy in the treatment of PTSD can be achieved with our new solid dose formulation. We look forward to taking advantage of the Fast Track designation and working closely with FDA in the design and initiation of the next Phase 2b study in PTSD patients.”

Fast Track designation is a FDA program intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition. A drug that receives Fast Track designation is eligible for some, or all, of the following:

- More frequent meetings with FDA to discuss the drug’s development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for accelerated approval and priority review, if relevant criteria are met
- Rolling Review, enabling a drug company to submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. NDA review usually does not begin until the drug company has submitted the entire drug application to the FDA.

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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.

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.