BIONOMICS INITIATES 7-DAY DOSING PHARMACOKINETIC STUDY OF BNC210 TABLET FORMULATION

Bionomics Limited (ASX:BNO, OTCQB:BNOEF), a global, clinical stage biopharmaceutical company, today announced the initiation of a 7-day dosing pharmacokinetic (PK) study in healthy volunteers using the newly developed solid dose tablet formulation of Bionomics’ lead drug candidate, BNC210. BNC210 has been granted Fast Track designation by the US Food and Drug Administration (FDA) for the treatment of Post-Traumatic Stress Disorder (PTSD) and other trauma-related and stress-related disorders.

The new solid dose formulation of BNC210 has been developed to overcome the failure of the liquid suspension formulation (which has a requirement to be taken with food) to provide sufficient blood exposure for efficacy in the first BNC210 Phase 2 PTSD trial, RESTORE, that read out in October 2018. Pharmacometric analysis of data from the RESTORE trial modelled an exposure-response relationship (between BNC210 blood levels and the primary endpoint measure in PTSD clinical trials, CAPS-5 severity scores), and the potential for BNC210 to treat PTSD symptoms provided that adequate blood levels can be achieved.

Pharmacokinetic data from the earlier single dose PK studies demonstrated that the tablet formulation does not have a requirement to be given with food and can reach blood levels required to achieve exposures predicted by pharmacometric modelling to give clinically meaningful and statistically significant results in PTSD patients. The results from this 7-day, twice daily dosing PK clinical trial in healthy subjects with the tablet formulation of BNC210 will be used to determine the dosing regimen of BNC210 that will be given to PTSD patients in a second Phase 2 clinical trial.

The tablets for this PK trial have been successfully manufactured, the study site has been formally initiated, and screening and selection of healthy volunteers for participation in the trial have commenced. Results from the study are expected in Q1 2021.

Dr. Errol De Souza, Executive Chairman of Bionomics said “We are pleased with the progress made in optimizing the BNC210 tablet formulation to overcome the limitations of the previous liquid suspension formulation. We continue on our previously communicated timelines to confirm the pharmacokinetic profile of the optimized BNC210 tablet to demonstrate that blood exposures predicted from the pharmacometric modelling are not only achieved but are maintained for a period of at least 7 days. In parallel, we are preparing for the start of the Phase 2 PTSD study with the new tablet formulation projected for mid-2021.”

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About Bionomics Limited
Bionomics (ASX: BNO, OTCQB:BNOEF) 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 development for initiation of a second Phase 2 trial for the treatment of PTSD, 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).

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.