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ASX ANNOUNCEMENT
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Positive BNC210 7-Day Dosing Pharmacokinetic Study Exceeds Blood Exposure Projected for Phase 2b PTSD Trial

- **BNC210 novel oral tablet formulation (900 mg given twice daily) exceeds blood exposure projected for upcoming Phase 2b PTSD trial**
- **BNC210 Phase 2b PTSD trial on target for start in mid-2021 with final dose selected**

Bionomics Limited (ASX: BNO, OTCQB: BNOEF, Germany: AU000000BNO5), a global, clinical stage biopharmaceutical company, today announced positive pharmacokinetic (PK) results from a 7-day dosing study in healthy volunteers using the newly developed solid dose oral tablet formulation of BNC210. BNC210 is a novel, negative allosteric modulator of the alpha 7 nicotinic acetylcholine receptor in development for the treatment of anxiety and stressor-related disorders, and in November 2019 was granted Fast Track designation by the US Food and Drug Administration (FDA) for the treatment of Post-Traumatic Stress Disorder (PTSD).

The 7-day dosing PK study in ten healthy volunteers (females and males) demonstrated that at a dose of 900 mg given twice daily, the tablet formulation of BNC210 had steady-state 12-hourly exposure levels ranging from 33-57 mg.h/L which exceed the 12-hourly blood exposure of ~25 mg.h/L predicted as necessary to meet the primary endpoints for effectiveness for treating PTSD patients in future clinical trials. A pharmacometric analysis of data from the first Phase 2 PTSD trial (RESTORE) that read out in October 2018, modelled an exposure-response relationship between BNC210 blood levels and CAPS-5 scores (the primary endpoint measure in PTSD trials), and the potential for BNC210 to treat PTSD symptoms provided that adequate blood exposure could be achieved.

The tablet formulation of BNC210 replaces the liquid suspension formulation used in RESTORE which did not provide sufficient blood exposure for efficacy in that Study. The BNC210 tablet will be easier for the PTSD trial participants to administer and, unlike the liquid suspension formulation, is not dependent on food intake for maximal absorption and is therefore expected to result in substantially less variable exposure in the patients in the next Phase 2b PTSD study. Furthermore, the recent PK results show that there is no gender-based difference in exposure and that BNC210 continues to be well-tolerated, even at the higher exposure levels achieved after 7 days of dosing in the healthy volunteers.

Dr. Errol De Souza, Executive Chairman of Bionomics said, “We are extremely pleased with the results of the 7-day PK study which demonstrate that we reach steady-state levels on the second

day following the start of twice daily dosing and that we not only meet but exceed the blood exposure predicted from the pharmacometric analysis as necessary for future trials. With the dose now selected, we can initiate manufacturing of the tablets, clinical site selection and regulatory filings in preparation for a Phase 2b trial with BNC210 in PTSD patients projected for mid-2021. The recently oversubscribed Private Placement of approximately \$16 million along with the proposed Entitlement Offer to our current shareholders will provide us with the funds necessary for BNC210 development.”

AUTHORISED BY THE BOARD OF DIRECTORS

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Clinical Trial Appendix:

Protocol No:	BNC210.011
Protocol Title:	A Multiple Dose Study Evaluating the Pharmacokinetics of an Oral Tablet Formulation of BNC210 in Healthy Volunteers
Study Design:	Single-centre, open label, 7-day multiple dosing study in healthy volunteers
Primary Objective:	To evaluate the pharmacokinetic profile at steady state of a tablet formulation of BNC210 for determining the dosing regimen to be used in future efficacy studies
Secondary Objectives:	To compare gender differences in the pharmacokinetic profile of a tablet formulation of BNC210; To assess the safety and tolerability of multiple doses of a tablet formulation of BNC210
Study Population:	Five healthy male and five healthy female volunteers aged 18-65

Clinical Trial Results Summary:

The 7-day dosing pharmacokinetic study in ten healthy volunteers (females and males) demonstrated that with the tablet formulation of BNC210 at a dose of 900 mg given twice daily:

- Steady state blood exposures were reached after one day of twice daily dosing;
- Steady state 12-hourly blood exposures reached a mean of 49 mg.hr/L (standard deviation: 7 mg.hr/L; range 33-57 mg.hr/L), exceeding the target 12-hourly exposure of 25 mg.hr/L projected from the pharmacometrics analysis;
- There were no gender differences in female and male blood exposure levels;
- BNC210 continues to be well-tolerated at these higher exposures

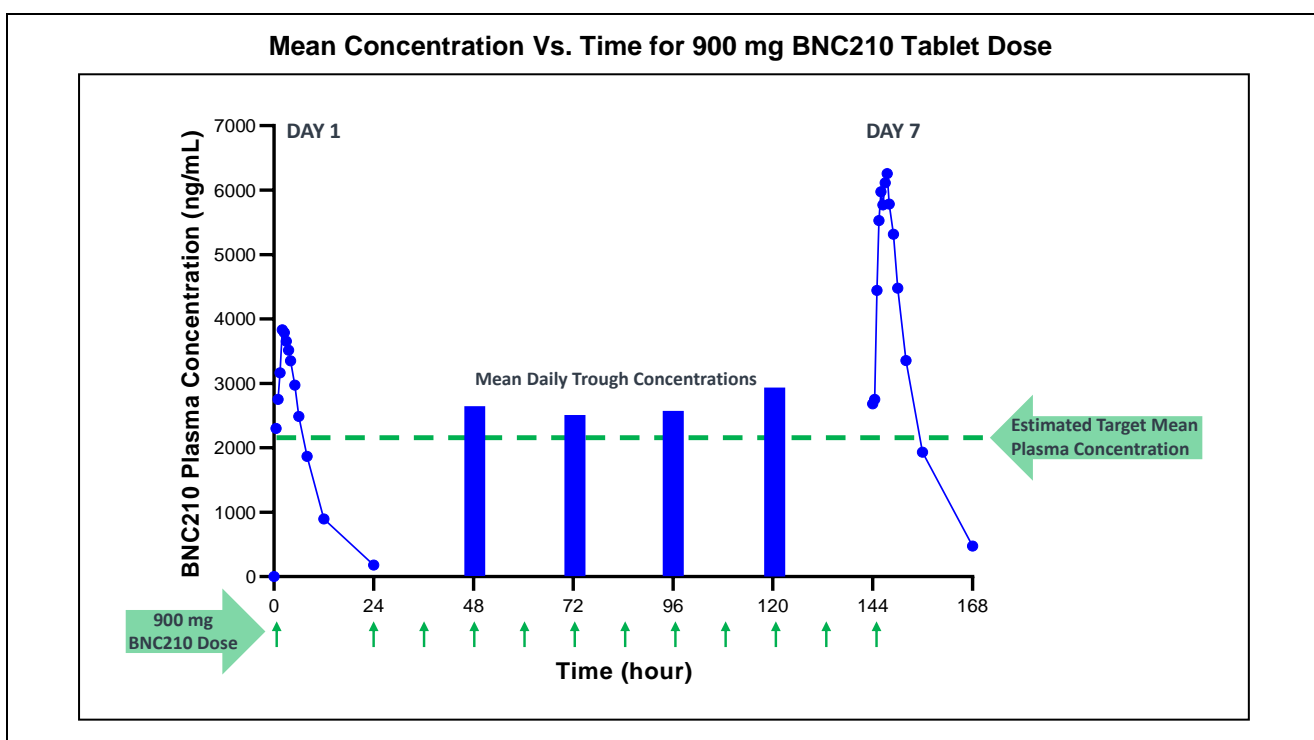


Figure 1. Healthy volunteers were given a 900 mg BNC210 dose on Day 1 (Time 0) and frequent blood samples were taken over the next 24-hour period. On Days 2-7 (Time 24-144 hours) subjects were dosed with 900 mg BNC210 twice daily and blood samples were taken once daily ('Daily Trough Concentrations'). On Day 7 (Time 144 hour), subjects were dosed in the morning and frequent blood samples were taken over the next 24-hour period. The data show that even the lowest 'Mean Daily Trough Concentrations' meet or exceed the 12-hourly blood exposure of 25 mg.hr/L (equivalent to a mean blood concentration of ~2,100 ng/mL) targeted by the pharmacometric analysis.

About Bionomics Limited

Bionomics (ASX: BNO, OTCQB: BNOEF, Germany: AU000000BNO5) 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 nicotinic acetylcholine receptor. Beyond BNC210, Bionomics has a strategic partnership with Merck & Co., Inc (known as MSD outside the United States and Canada) with two drugs in early stage clinical trials for the treatment of cognitive deficits in Alzheimer's disease.

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.