ABN 53 075 582 740

ASX ANNOUNCEMENT
26 September 2019

BNC210 Solid Dose Formulation Achieves Blood Levels Required for Future Development in PTSD

Bionomics Limited (ASX:BNO, OTCQX:BNOEF), a global, clinical stage biopharmaceutical company discovering and developing a deep pipeline of novel drug candidates targeting ion channels, is pleased to announce positive results from a pharmacokinetic study in healthy volunteers using the newly developed solid dose formulation of Bionomics' lead drug candidate, BNC210.

The study demonstrates that the solid dose of BNC210 achieves the blood levels predicted as necessary to meet the primary endpoints for effectiveness for treating Post-Traumatic Stress Disorder (PTSD) patients in future clinical trials.

The study is the culmination of efforts designed to overcome the failure of the liquid suspension formulation to provide sufficient blood exposure for efficacy in the Phase 2 PTSD trial, RESTORE, that read out in October 2018. As reported on 18 February 2019, the liquid suspension formulation of BNC210 used in the RESTORE trial was required to be taken with food, gave variable absorption and consequently lower exposure than expected. However, a pharmacometric analysis of the PTSD trial data showed an exposure-response relationship (between BNC210 blood levels and CAPS-5 scores, the primary endpoint measure in PTSD trials), and the potential of BNC210 to treat PTSD symptoms provided that adequate blood levels could be achieved (Area Under the Curve or AUC ~25 mg.h/L).

These new pharmacokinetic data from the single ascending doses of BNC210, along with data reported earlier this year demonstrating that the solid dose formulation can overcome the "food effect", show that the solid dose formulation of BNC210 can reach blood levels required to achieve exposures predicted to give clinically meaningful and statistically significant changes from placebo on Total CAPS-5 scores (Table 1). The plasma concentrations and exposures measured in fasted healthy volunteers also increased in a dose proportional manner, demonstrating improved dose linearity with the solid dose formulation compared to the liquid suspension (Figure 1).

BNC210 was well tolerated at the exposure levels reached in the healthy volunteers in this study.

Bionomics recently attended a supportive Type C meeting with the FDA to discuss the further development of BNC210 using the solid dose formulation for the treatment of PTSD and subsequently submitted a request for Fast Track designation for BNC210.

The results of this pharmacokinetic clinical trial show that the new solid dose formulation achieves the targeted blood levels to support further development of BNC210 for the treatment of PTSD.

FOR FURTHER INFORMATION PLEASE CONTACT:

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

Clinical Trial Appendix

STUDY REFERENCE	BNC210.010
STUDY TITLE	The pharmacokinetics and clinical tolerability of ascending single doses of an oral tablet formulation of BNC210 in healthy male volunteers
PRIMARY OBJECTIVE	To compare the pharmacokinetic profile of ascending doses of a tablet formulation of BNC210
SECONDARY OBJECTIVE	To compare the safety and tolerability of ascending doses of a tablet formulation of BNC210
STUDY DESIGN	This is a single-centre study where over three dosing periods, the same five subjects under fasted conditions are administered single oral doses of BNC210 in increasing strength (600, 900 and 1200 mg), with a minimum 5-day washout between dose administrations.
STUDY POPULATION	Five healthy male volunteers

Clinical Trial Results

Table 1: Plasma exposures obtained with four single doses of BNC210 tablets in fasted, healthy volunteers

BNC210 Dose	Plasma Exposure (AUC)
300 mg	11 mg.h/L[a]
600 mg	20 mg.h/L
900 mg	27 mg.h/L
1200 mg	38 mg.h/L

[a] Data from the first tablet pharmacokinetic study reported 18 February 2019

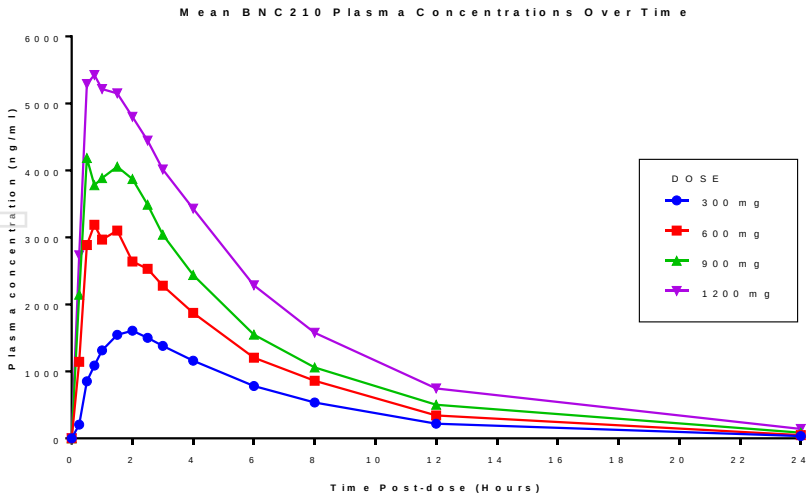

Figure 1: BNC210 tablets have been evaluated at four doses in fasted, healthy volunteers (300[a], 600, 900 and 1200 mg). The plasma concentrations increased in a dose proportional manner, demonstrating that the solid dose formulation of BNC210 removes the food effect and improves dose linearity. ([a] Data from the first tablet pharmacokinetic study reported 18 February 2019)

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.