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CREATING INNOVATIVE THERAPIES
FOR CNS DISORDERS.

BNC210 Update

BNO (Australia: ASX)
BNOEF (USA: OTCQX)

26 June 2019

Central Nervous System (CNS)

Safe Harbor Statement

Factors Affecting Future Performance

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BNC210: Introduction and Overview

- BNC210, is a novel, orally-administered, first-in-class, negative allosteric modulator of the α7 nicotinic acetylcholine receptor, in development for anxiety, panic, agitation, and PTSD:
  - Positive data from Phase 2 trial in Generalised Anxiety Disorder (GAD) patients - reported in September 2016
  - Phase 2 trial in Post-Traumatic Stress Disorder (PTSD) did not reach primary endpoint on a dosage basis - reported in October 2018
  - Additional work undertaken on a drug exposure-response analysis established a relationship for CAPS-5* Total Symptom Severity scores (p-value<0.01), where higher exposures were related to a larger effect – reported in February 2019
  - Identified an improved solid dose formulation of BNC210 with potential to overcome the "food effect" of the liquid suspension formulation used in the previous clinical trials – reported in February 2019
  - Phase 2 exploratory trial in treatment of agitation in elderly conducted in Australia
- Agenda for Call:
  - Report top line data of Phase 2 exploratory trial in treatment of agitation in elderly
  - Define next steps and timelines for the BNC210 solid dose formulation development and FDA guidance for PTSD including design of a further trial and Fast Track designation

*CAPS-5: Clinician Administered PTSD Scale for DSM-5

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BNC210.008
An Exploratory Phase 2 Study to Assess Efficacy and Safety of BNC210 in Hospitalised Elderly Patients with Agitation

Top Line Data

Agitation in the Elderly

- Treatment of agitation in the elderly is a significant unmet need
- Current medications have significant side effects and increased mortality
- BNC210 is a safe molecule - demonstrated in non-clinical studies and clinical studies in over 350 subjects
- BNC210 has demonstrated rapid onset of action in non-clinical and clinical studies
- Properties of BNC210 indicate potential as a therapeutic for treatment of agitation in the elderly

Study BNC210.008: An Exploratory Phase 2 Trial to Assess Efficacy and Safety of BNC210 in Hospitalised Elderly Patients with Agitation

- This exploratory Phase 2 study was designed to:
  - Assess the feasibility of conducting a study in acute agitation in hospitalised elderly patients,
  - Obtain initial signals of efficacy of BNC210 on agitation in the elderly in an acute setting with short duration of treatment, and
  - Evaluate safety of BNC210 in the elderly patient population.
- The study was conducted in patients under the care of a specialist Geriatrician
- Environment was suitable for high quality and frequent assessment of therapeutic response
- The simple design required few additional procedures over standard-of-care
- BNC210 was provided as an oral liquid suspension (administered with food) which is a convenient formulation to administer to elderly patients
- Being exploratory in nature, it was not a powered study

Study BNC210.008 – Summary Study Design

Study Design	• Randomised, double-blind, placebo controlled, parallel dosing • BNC210 300 mg and placebo (1:1) • Twice daily administration as a suspension formulation • 5 days treatment; 2 days follow up • Recruited 38 participants; 5 Australian sites
Key Selection Criteria	• Hospitalised elderly patients under the care of a specialist Geriatrician • Presenting with agitation requiring intervention in addition to standard-of-care behavioural management
Outcome Measures	• **Pittsburgh Agitation Scale (PAS):** Observations of aberrant vocalisation, motor agitation, aggressiveness and resisting care • **Clinical Global Impression scale (CGI):** A tool used in psychiatry to measure illness severity and global improvement or change • **Safety:** Adverse event reporting; safety labs; physical examinations; vital signs • **Exposure:** BNC210 plasma concentration

Participant Demographics

- 38 randomised (includes 2 participants who were withdrawn prior to receiving study drug)
- 36 included in the efficacy and safety analysis sets

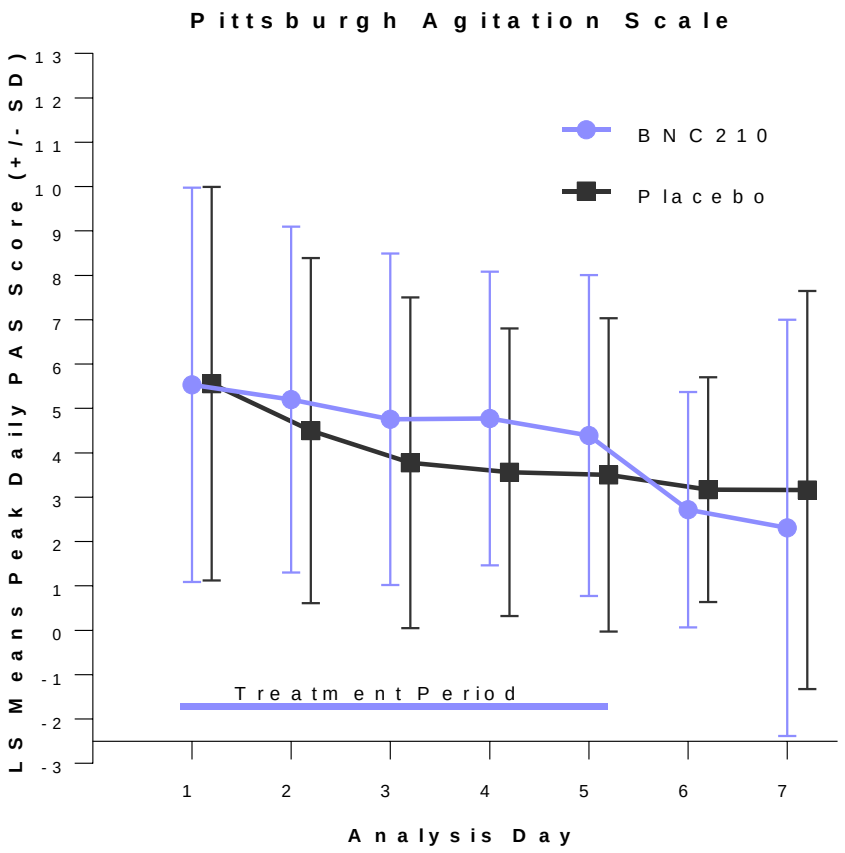
		BNC210 N=19	Placebo N=19
Age (years)	Mean	85	82
	Median	84	83
	SD	5.9	7.7
	Minimum	75	60
	Maximum	94	92
Gender (n)	Female	10	7
	Male	9	12

Primary Efficacy Objective – Change in Agitation as Measured by the Pittsburgh Agitation Scale (PAS)

Comparison of LSMeans Peak Daily PAS scores for BNC210 and placebo treated participants over the 5-day treatment period shows gradual improvement (as expected), but no evidence of a treatment effect [using Mixed Model for Repeat Measures (MMRM)]

PAS agitation scores were also analysed as:
(a) mean daily scores,
(b) daily area-under-the-curve,
(c) summed agitation intensity (change in agitation intensity over time), and
(d) time to a state of non-agitation

- No differences in the group means for BNC210 and placebo were seen
- All analyses were repeated with sleep periods excluded, and no differences were seen



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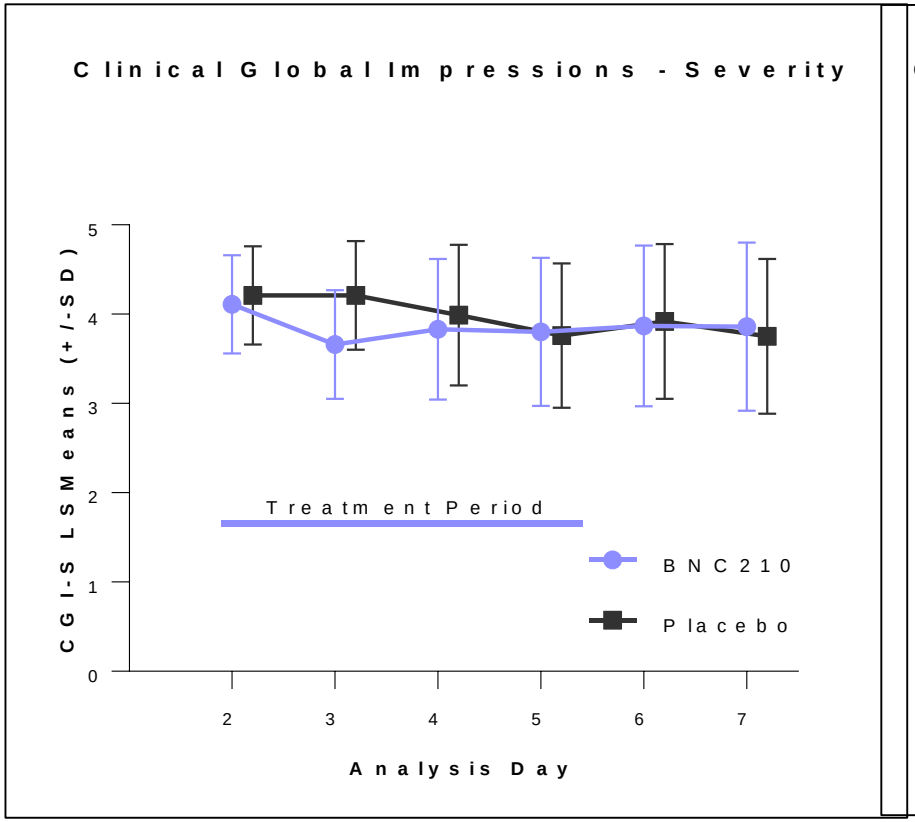
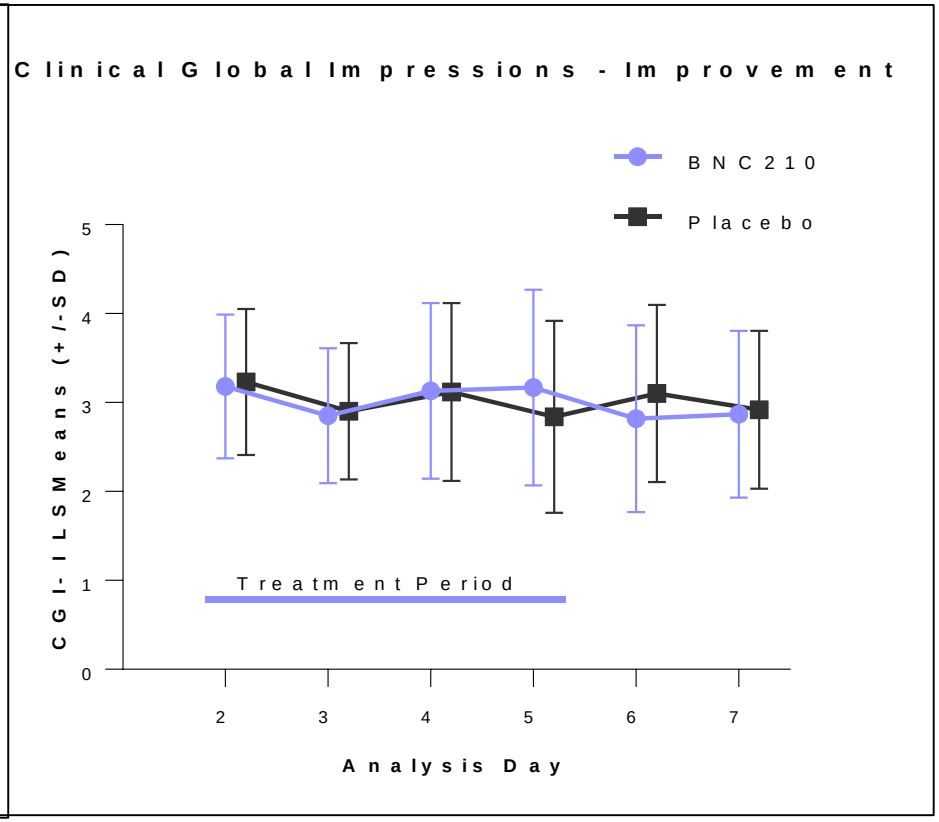
Secondary Efficacy Objective – Change in Global Function as Measured by the Clinical Global Impressions (CGI) Scale

There were no treatment effects seen when comparing the LSMeans CGI scores (severity and improvement) for BNC210 and placebo over the 5-day treatment period (using MMRM)





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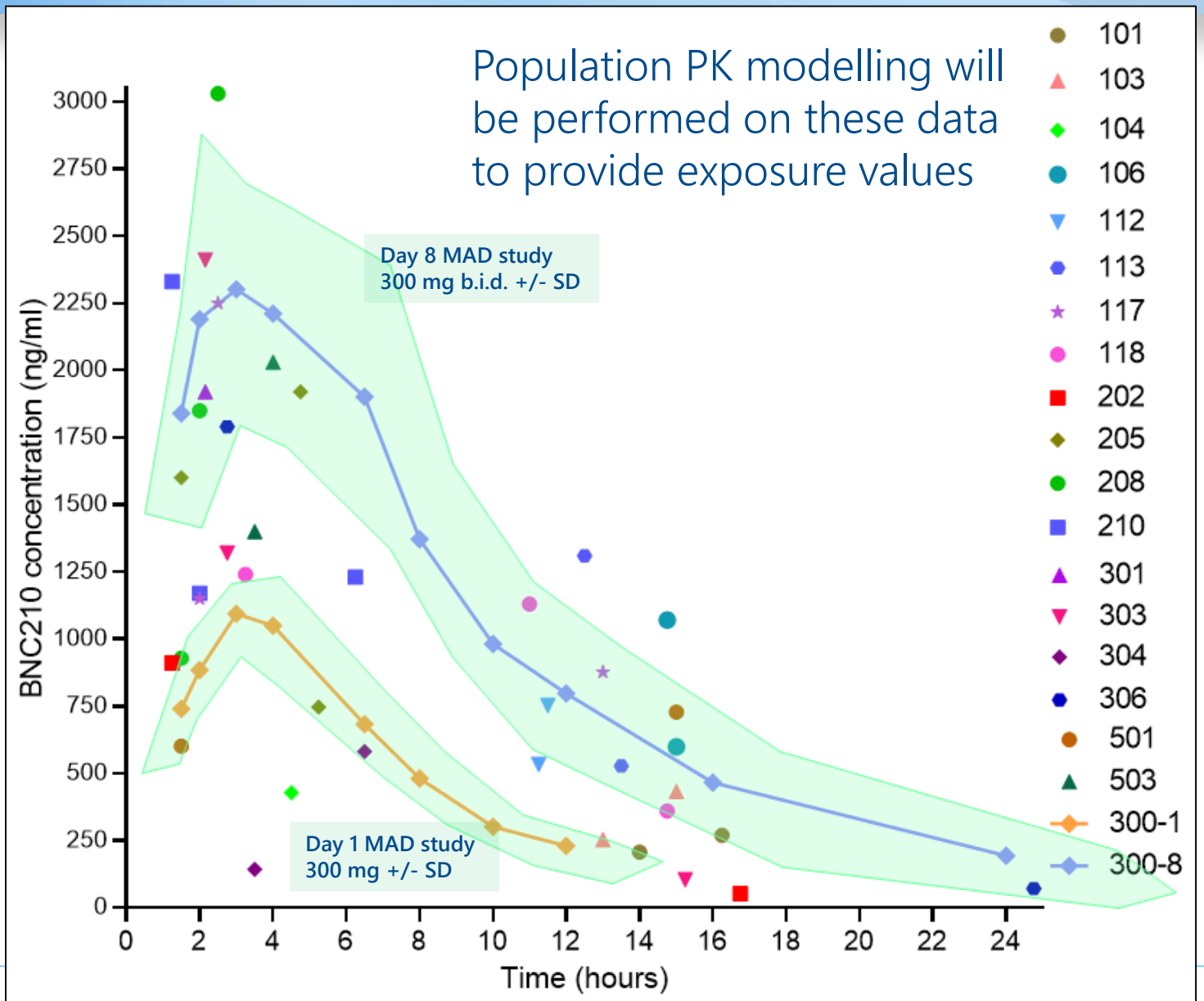
Blood Levels in Elderly Patients were in the Range of Those Seen in Multiple Ascending Dose (MAD) Study in Healthy Volunteers



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Safety Summary

The safety data from Study BNC210.008 is an important addition to the BNC210 safety dossier

- The trial was conducted in an acutely ill and frail elderly population who are prone to medication-related adverse effects
- There was no pattern of adverse events which were thought to be at least "possibly" related to BNC210 treatment in comparison to placebo
- Potential central nervous system symptoms common to other anti-anxiety and anti-agitation drugs such as drowsiness were reported at the same frequency for BNC210 and placebo treatments
- These observations are consistent with BNC210's excellent safety profile, in which no pattern of adverse effects related to BNC210 treatment have been identified in animal studies or clinical trials

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BNC210 Development For the Treatment of Post-Traumatic Stress Disorder

Next Steps

Overall Conclusions from the PTSD Trial

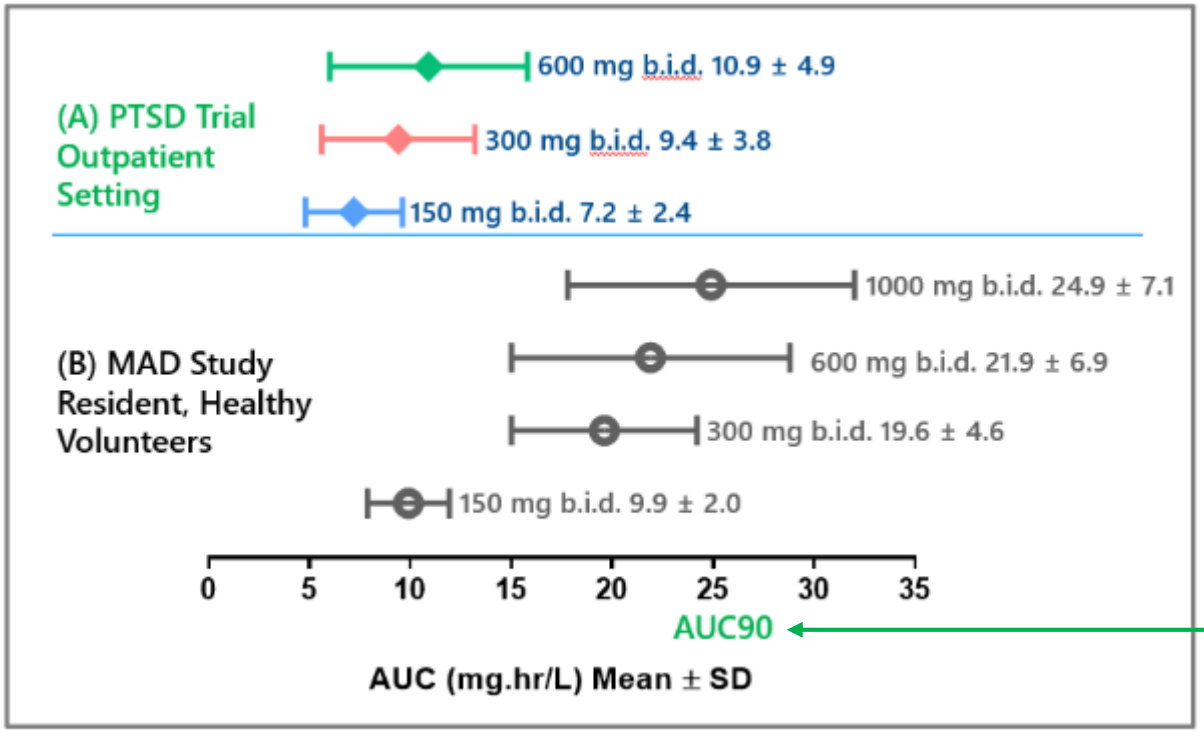
- No effect on primary CAPS-5 endpoint based on dosage-response analysis
- Additional data analysis conducted in Sweden by Pharmetheus AB established a drug exposure-response relationship for CAPS-5 Total Symptom Severity scores (p-value<0.01), where higher exposures were related to a larger effect

Mats O Karlsson, Professor in Pharmacometrics at Uppsala University, states:

"Exposure-response modelling has shown the potential for BNC210 to have significant benefit in PTSD provided that adequate blood levels are achieved. This analysis provides a basis for optimal design of future trials to demonstrate efficacy."

Phase 2: PTSD Trial Results Indicated That Outpatients Were "Under Exposed" During The Study

- BNC210 was dosed as a liquid suspension formulation which is dependent on administration with (fatty) food for maximum absorption
- Modelled exposure (AUC) values for patients for 300 and 600 mg doses b.i.d. (twice daily) were <50% of those seen with BNC210 in its Multiple Ascending Dose study in healthy volunteers using the same doses and formulation



Estimated required exposure level for patient benefit

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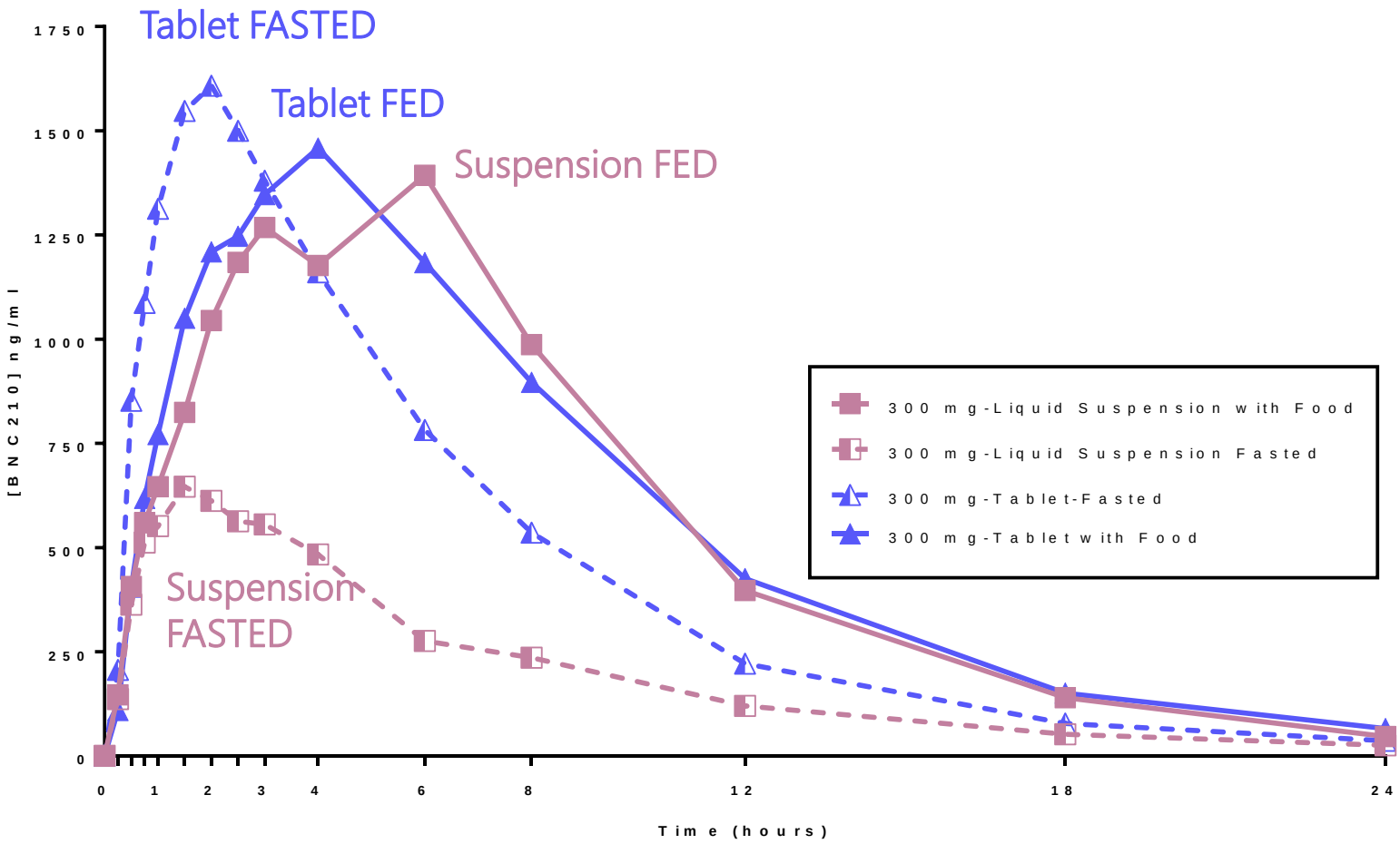
A Tablet Formulation of BNC210 Has Been Developed to Overcome the Reliance on Fatty Food for Absorption



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What's Next for BNC210 Development?

- Meeting with & feedback from the FDA pending
- Human Single Ascending Dose (SAD) pharmacokinetic study to identify the BNC210 dose (25 mg*hr/L)

CY4Q19

Pending positive feedback from FDA and ability to achieve 25 mg*hr/L in SAD study

- Optimisation of tablet formulation
- Human Multiple Ascending Dose (MAD) pharmacokinetic studies to confirm steady-state BNC210 levels of 25 mg*hr/L
- API and Tablet manufacture for trial
- Prepare for Phase 2b PTSD Trial

CY4Q20

Summary & Next Steps for BNC210

BNC210 Agitation	▪ Top line data did not meet primary or secondary efficacy endpoints ▪ Confirmed the good safety profile of the drug in elderly patients; exposure analysis will further add to safety database
BNC210 PTSD	▪ Awaiting FDA guidance on next steps for BNC210 for PTSD including the design of a further trial and whether BNC210 is eligible for Fast Track designation
BNC210 Formulation Development	▪ Evaluate the improved solid dose formulation of BNC210 in single ascending dose study in healthy volunteers to confirm achievement of blood levels of 25 mg*hr/L predicted to be necessary for treatment of PTSD patients based on PK-PD modeling analysis
Pipeline	▪ Potential for additional therapeutic candidate prior to CY3-4Q19

- Validated Platform – Merck partnership and shareholding
- Robust pipeline of first in class ion channel candidates addressing significant unmet need in Bionomics' areas of strength in CNS disorders
- Bionomics will continue to evaluate partnership opportunities in parallel