



## **Bionomics Completes Last Patient Last Visit in the Phase 2b ATTUNE Study for Post-Traumatic Stress Disorder (PTSD) and Confirms Expected 2023 Milestones with its Lead Asset BNC210**

August 23, 2023

- ***The last patient last visit has been completed in the Phase 2b ATTUNE study of BNC210 for the treatment of PTSD***
- ***Topline results from Phase 2b ATTUNE study of BNC210 in patients with PTSD are expected by the end of September 2023***
- ***An end-of-phase 2 (EoPh2) meeting with the U.S. Food and Drug Administration (FDA) has been scheduled for September 2023 to review results from the Phase 2 PREVAIL study in patients with Social Anxiety Disorder (SAD) and to obtain feedback on a proposed Phase 3 registrational program***
- ***Bionomics is scheduled to delist from the Australian Securities Exchange on 28 August 2023***

ADELAIDE, Australia, and CAMBRIDGE, Mass., Aug. 23, 2023 (GLOBE NEWSWIRE) -- Bionomics Limited (Nasdaq: BNOX | ASX: BNO) (Bionomics or Company), a clinical-stage biotechnology company developing novel, first-in-class, allosteric ion channel modulators to treat patients suffering from serious central nervous system ("CNS") disorders with high unmet medical need, today announced that the last patient last visit has been completed in its Phase 2 ATTUNE study in PTSD, and disclosed timing of the End of Phase 2 (EoPh2) meeting to review advancing BNC210 into Phase 3 program in patients with SAD.

"We continue our strong momentum with our fast track designated BNC210, with a robust clinical and regulatory milestone-rich year in both SAD and PTSD, two highly prevalent neuropsychiatric disorders with significant unmet needs," said Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Bionomics. "I would like to thank study participants, their families, our clinical site investigators and their staff and our clinical team for their contributions towards achieving completion of the ATTUNE study. We also look forward to our EoPh2 meeting with the FDA next month, where we will discuss our promising results from the PREVAIL study in SAD and the proposed Phase 3 clinical program."

The Phase 2b ATTUNE study (NCT04951076) is a double-blind, placebo-controlled, randomized study of twice daily BNC210 as monotherapy treatment for PTSD. The primary endpoint is change in a Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) total symptom severity scores from baseline to week 12 compared to placebo. Secondary endpoints include change from baseline to week 12 compared to placebo on the PTSD-checklist (PCL-5), anxiety (Hamilton Anxiety Rating Scale, HAM-A), depression (Montgomery-Asberg Depression Rating Scale, MADRS), Clinician Global Impression (CGI), Patient Global Impression (PGI), sleep (Insomnia Severity Index, ISI) and disability (Sheehan Disability Scale, SDS) scales. Approximately 200 participants have been enrolled at 27 sites in the United States and 7 sites in the United Kingdom, and topline results are anticipated by the end of September 2023.

The EoPh2 meeting to discuss advancing BNC210 into Phase 3 development as an acute treatment for SAD has been scheduled for mid-September 2023. At this meeting, Bionomics will discuss with the FDA its plans for a Phase 3 program that would support the submission of a new drug application for BNC210 for the treatment of SAD. The Company believes that the results from Phase 2 PREVAIL study support the progression of BNC210 into Phase 3 and plans to provide an update by the end of 2023 following the receipt of formal meeting minutes from the FDA.

Additionally, Bionomics is scheduled to delist from the Official List of the Australian Securities Exchange on 28 August 2023. The Company will remain an Australian incorporated company and will maintain its listing of ADSs on Nasdaq under the trading symbol 'BNOX'.

### **FOR FURTHER INFORMATION PLEASE CONTACT:**

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### **About Bionomics Limited**

Bionomics (ASX:BNO, NASDAQ:BNOX) is a clinical-stage biotechnology company developing novel, first-in-class, allosteric ion channel modulators to treat patients suffering from serious central nervous system ("CNS") disorders with high unmet medical need. Bionomics is advancing its lead drug candidate, BNC210, an oral, proprietary, selective negative allosteric modulator of the  $\alpha 7$  nicotinic acetylcholine receptor, for the acute treatment of Social Anxiety Disorder (SAD) and chronic treatment of Post-Traumatic Stress Disorder (PTSD). 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 and other central nervous system conditions. Bionomics' pipeline also includes preclinical assets that target Kv3.1/3.2 and Nav1.7/1.8 ion channels being developed for CNS conditions of high unmet need. [www.bionomics.com.au](http://www.bionomics.com.au)

### **Forward-Looking Statements**

Bionomics cautions that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "potential," "continue" or "project" or the negative of these terms or other comparable terminology are intended to identify forward-looking statements. These

statements include the Company's plans to advance the development of its product candidates, the timing of achieving any development or regulatory milestones, and the comparability and potential of such product candidates, including to achieve any benefit or profile or any product approval or be effective. The inclusion of forward-looking statements should not be regarded as a representation by Bionomics that any of its plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in the Company's business and other risks described in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 20-F filed with the SEC on October 14, 2022, and its other reports. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Bionomics undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. Further information regarding these and other risks is included in Bionomics' filings with the SEC which are available from the SEC's website ([www.sec.gov](http://www.sec.gov)) and on Bionomics' website ([www.bionomics.com.au](http://www.bionomics.com.au)) under the heading "Investor Center." All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.