Bionomics Ltd Logo

Bionomics Announces the Completion of Enrollment in Phase 2b ATTUNE Clinical Trial of BNC210 in Patients with Post-Traumatic Stress Disorder (PTSD)

April 27, 2023

Topline results expected in Q3 2023

ADELAIDE, Australia, April 27, 2023 (GLOBE NEWSWIRE) -- Bionomics Limited (Nasdaq: BNOX | ASX: BNO) (Bionomics or Company), a clinical-stage biopharmaceutical company developing novel allosteric ion channel modulators for serious central nervous system (CNS) disorders with high unmet medical need, today announced that the Company has completed target enrollment of approximately 200 participants in its randomized, double-blind, placebo-controlled, multi-center Phase 2b ATTUNE clinical trial evaluating BNC210 in Post-Traumatic Stress Disorder (PTSD). Topline results are expected in the third quarter of 2023.

“2023 is on track to be a pivotal and milestone-rich year for Bionomics. Completing enrollment in the Phase 2b ATTUNE trial paves the way for a timely topline readout and highlights our mid- and late-stage clinical development capabilities. We would like to extend our continuing gratitude to trial participants, their families and to our investigators and their staff for their shared commitment to our trial and to addressing the needs of patients with CNS diseases,” said Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Bionomics. “Our momentum continues to grow following promising results with BNC210 in our Phase 2 PREVAIL study in Social Anxiety Disorder (SAD). Together, our SAD and PTSD programs hold the promise of transforming the treatment paradigm in two highly prevalent neuropsychiatric disorders.”

About ATTUNE

ATTUNE is a Phase 2b double-blind, placebo-controlled, randomized study of 900 mg BNC210 given twice daily as monotherapy treatment for PTSD. Study participants are randomized 1:1 to receive either placebo or BNC210. Key inclusion criteria include being 18-75 years of age, having a current PTSD diagnosis with a Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) total symptom severity score of ≥ 30 at screening and baseline, and ≤ 25% decrease in CAPS-5 score from screening to baseline. The primary endpoint is change in 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). Approximately 200 participants have been enrolled at 27 sites in the United States and 7 sites in the United Kingdom. For more information, see ClinicalTrials.gov Identifier: NCT04951076.

About Post Traumatic Stress Disorder

Post-Traumatic Stress Disorder (PTSD) is a psychiatric condition that may occur in people who have experienced or witnessed a traumatic event, series of events or set of circumstances. People with PTSD have intense, disturbing thoughts and feelings related to their experience that persist long after the traumatic event has ended. They may relive the event through flashbacks or nightmares, may feel sadness, fear or anger and may experience a sense of detachment or estrangement from others. As a result of these feelings, people with PTSD may avoid situations or people that remind them of the traumatic event, and they may have strong negative reactions to commonplace stimuli such as loud noises or an accidental touch.

About BNC210

BNC210 is a negative allosteric modulator of the α7 nicotinic acetylcholine receptor under development for the treatment of SAD and PTSD. BNC210 has been given FDA Fast Track designation for treatment of PTSD and other trauma and stressor related disorders and for acute treatment of SAD and other anxiety related disorders.

FOR FURTHER INFORMATION PLEASE CONTACT:

General
Ms. Suzanne Irwin
Company Secretary
+61 8 8150 7400
CoSec@bionomics.com.au

Investor Relations
Mr. Connor Bernstein
Vice President, Strategy and Corporate Development
+1 (650) 524-5143
cbernstein@bionomics.com.au

Investor Relations
Kevin Gardner
kgardner@lifesciadvisors.com

About Bionomics Limited

Bionomics (ASX:BNO, NASDAQ:BNOX) is a clinical-stage biopharmaceutical company developing novel, allosteric ion channel modulators designed to transform the lives of patients suffering from serious CNS disorders with high unmet medical need. Bionomics is advancing its lead drug candidate, BNC210, an oral, proprietary, selective negative allosteric modulator of the α7 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.

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) and on Bionomics' website (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.