Bionomics Announces Successful End-of-Phase 2 Meeting with the FDA on the Development of BNC210 in Post-Traumatic Stress Disorder

Jul 31, 2024

- ***Successful End-of-Phase 2 (EoP2) meeting with U.S. Food and Drug Administration (FDA) provides a potential path to New Drug Application (NDA) submission for BNC210 for post-traumatic stress disorder (PTSD) with a single Phase 3 trial***

- ***Company received favorable FDA feedback on the Phase 3 study design and safety monitoring plans required for registration***
- ***Company plans to initiate the Phase 3 program in Q4 2024***
- ***A conference call and webcast presentation to discuss the outcomes will be held today at 8:00 a.m. ET, details below***

ADELAIDE, Australia and CAMBRIDGE, Mass., July 31, 2024 (GLOBE NEWSWIRE) -- Bionomics Limited (Nasdaq: BNOX) (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 the favorable outcomes of an EoP2 meeting with the FDA, supporting the advancement of its lead asset BNC210 for the treatment of PTSD into Phase 3 based on the positive results of the recently completed Phase 2b ATTUNE study.

“We are very pleased with the outcomes of our EoP2 meeting with the FDA and look forward to initiating our transformation into a pre-commercial organization,” said Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Bionomics. “This milestone is another testament to the strong clinical profile of BNC210, which has demonstrated efficacy across multiple stress and anxiety disorders. We believe BNC210 can potentially transform the standard-of-care in PTSD, a serious disorder impacting about 7% of Americans during their lifetime. Followings the recent initiation of the Phase 3 trial of BNC210 in social anxiety disorder (AFFIRM-1), we look forward to starting a Phase 3 trial in PTSD by the end of 2024.”

The company presented the clinical plans to registration, that alongside the positive Phase 2b ATTUNE trial include a single additional Phase 3 trial to evaluate two dose levels of BNC210 in a 12-week randomized, double-blind, placebo-controlled trial with a 52-week open-label extension. The meeting, held on June 26, 2024, was centered around the design of the Phase 3 trial that if successful may enable review of the NDA submission. Key outcomes from the discussion on the trial design included:

1. Agreement was reached on the use of Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) as the primary endpoint measure and the Clinical Global Impressions Severity scale (CGI-S) as a key secondary endpoint measure in the placebo-controlled part of the study.
2. Agreement was reached that in addition to the efficacious dose of 900 mg twice daily (BID) a lower dose of BNC210 that strikes the right balance between maintenance of efficacy and safety related to liver function tests (LFT) findings will be tested. Full justification for the proposed lower dose of 600 mg twice daily (BID) will be included in the final Ph3 PTSD trial protocol.
3. High-level agreement was reached on study participant characteristics and sample size assumption methodology.
4. The company received guidance related to the proposed hepatic safety monitoring plan, including monitoring for excessive alcohol use that will be implemented in the planned Phase 3 trial.

The Company plans to submit the full Phase 3 protocol for FDA review prior to trial initiation.

The company is finalizing the full study protocol and anticipates beginning the Phase 3 program in PTSD in Q4 2024.

Conference Call and Webcast Presentation

Bionomics management team will host a conference call and webcast presentation today at 8:00 a.m. ET provide a corporate update and discuss the registrational path forward for BNC210. A live Q&A session will follow the brief presentation. To participate in the conference call, please dial 1-877-407-0792 (U.S.) or 1-201-689-8263 (international) and use conference ID 13748183. To access the webcast presentation, please click here.

FOR FURTHER INFORMATION PLEASE CONTACT:

General
Rajeev Chandra
Company Secretary
CoSec@bionomics.com.au

Investor Relations
Kevin Gardner
kgardner@lifesciadvisors.com

Investor Relations
Chris Calabrese
ccalabrese@lifesciadvisors.com

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

Formulated as an oral solid tablet BNC210 is a negative allosteric modulator of the α7 nicotinic acetylcholine receptor under development for the treatment of social anxiety disorder (SAD) and post-traumatic stress disorder (PTSD). BNC210 has been given FDA Fast Track designation for acute treatment of SAD and other anxiety related disorders, and for treatment of PTSD and other trauma and stressor related disorders.

About Bionomics Limited

Bionomics (NASDAQ: BNOX) is a clinical-stage biotechnology company developing novel, potential 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 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 CNS 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

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. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to: the closing of each tranche of the Company's private placement financing, the achievement of certain milestones for the various tranches, the timely funding to the Company by each investor in the private placement, the timing, size and expectation of the closing of the private placement; and expectations regarding market conditions, the satisfaction of customary closing conditions related to the private placement and the anticipated use of proceeds therefrom; and the Company's expectation that its current cash, cash equivalents, and marketable securities will fund our operations into the third quarter of 2025. 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, but not limited to, the Company's Annual Report on Form 20-F filed with the SEC, 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, uncertainties and other factors is included in Bionomics' filings with the SEC, copies of 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. Bionomics expressly disclaims all liability in respect to actions taken or not taken based on any or all the contents of this press release.

Source: Bionomics Ltd