Bionomics Announces Positive Topline Results from the Phase 2b ATTUNE Clinical Trial of BNC210 in Patients with Post-Traumatic Stress Disorder (PTSD)

September 28, 2023

ATTUNE trial met its primary endpoint showing BNC210 treatment led to a statistically significant reduction in total PTSD symptom severity at 12 weeks.

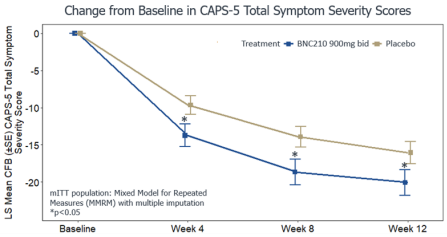
Statistically significant secondary endpoints showed improvements in depressive symptoms and sleep.

BNC210 was well-tolerated with a safety profile supporting chronic administration.

Company plans to engage with the U.S. Food and Drug Administration (FDA) to discuss the registrational path for BNC210 in PTSD.

Webcast and conference call will be held today at 8:00 AM EST (10:00 PM AEST). Please click on the link to register: https://lifescievents.com/event/bnox/

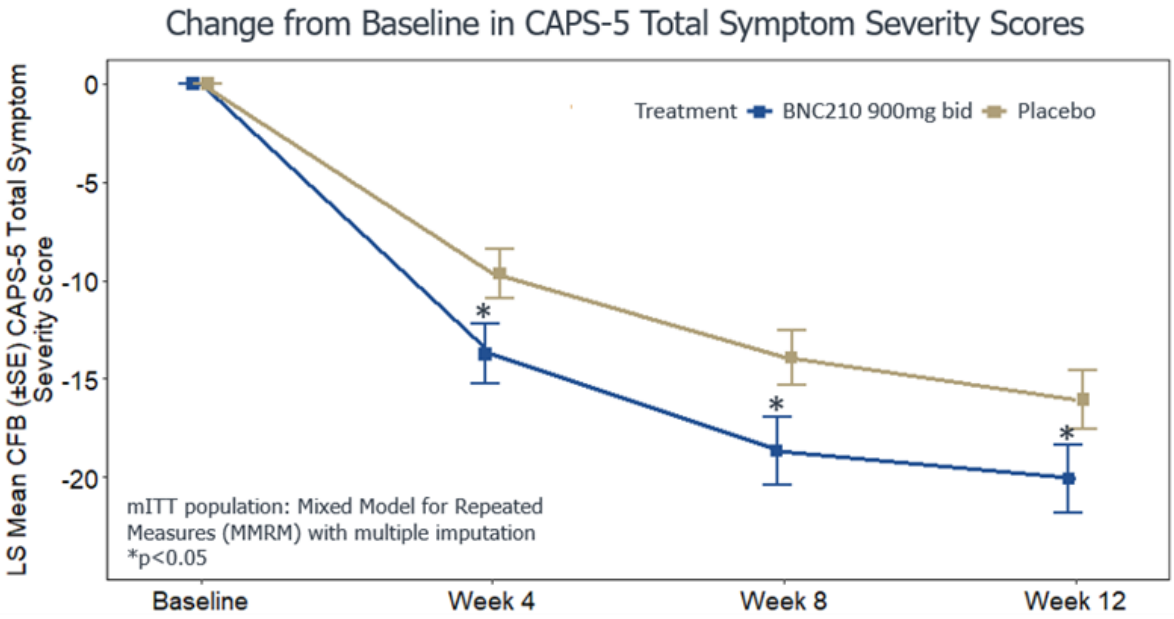
Change from Baseline in CAPS-5 Total Symptom Severity Scores



Change from Baseline in CAPS-5 Total Symptom Severity Scores

ADELAIDE, Australia, and CAMBRIDGE, Mass., Sept. 28, 2023 (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 positive topline results from its Phase 2b ATTUNE trial of BNC210 for the treatment of PTSD, as described more fully below.

ATTUNE is a double-blind, placebo-controlled Phase 2b trial conducted in a total of 34 sites in the United States and the United Kingdom, with 212 enrolled patients, randomized 1:1 to receive either twice daily 900 mg BNC210 as a monotherapy (n=106) or placebo (n=106) for 12 weeks. The trial met its primary endpoint of change in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) total symptom severity score from baseline to Week 12 (p=0.048). A statistically significant change in CAPS-5 score was also observed at Week 4 (p=0.015) and at Week 8 (p=0.014).



Treatment with BNC210 also showed statistically significant improvement both in clinician-administered and patient self-reporting in two of the secondary endpoints of the trial. Specifically, BNC210 led to significant improvements at Week 12 in depressive symptoms (p=0.040) and sleep (p=0.041) as measured by Montgomery-Åsberg Depression Rating Scale (MADRS) and Insomnia Severity Index (ISI), respectively. BNC210 also showed signals and trends across visits in the other secondary endpoints including the clinician and patient global impression - symptom severity (CGI-S, PGI-S) and the Sheehan Disability Scale (SDS).

"We are excited about the results of the ATTUNE trial that delivered a positive dataset with treatment effects considerably higher than currently approved therapies. We believe these results will enable FDA discussions for the registrational path of BNC210 in PTSD, which in an indication with high unmet need", said Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Bionomics. "I am thankful to the patients, their families, and the clinical teams who participated and contributed to this study. These results, together with the results from earlier this year in social anxiety disorder,

and the recently completed Phase 3-enabling End-of-Phase 2 meeting with the FDA on social anxiety disorder, positions BNC210 as a compelling late-stage experimental therapeutic for multiple prevalent neuropsychiatric diseases with high unmet need."

Treatment with 900 mg twice daily BNC210 had a favorable safety and tolerability profile. The most common (>5% of subjects in each group) reported adverse events, including headache, nausea, and fatigue, which were consistent with previous studies with BNC210. A hepatic enzyme increase was observed in 14 (13.3%) patients treated with BNC210 vs 2 (0.19%) in the placebo group; the abnormal results were not associated with hepatic injury and in most cases were resolved without drug discontinuation.

"There is great unmet medical need for safe and effective treatments for the large population of patients suffering with PTSD worldwide. Despite the clinical heterogeneity of PTSD, the results of ATTUNE demonstrated broad benefits with BNC210 across a number of symptoms. This a promising step forward for patients with PTSD, where the majority do not achieve clinical remission with current therapies and there have been no newly approved therapies in the past 20 years." commented Murray B. Stein M.D., M.P.H., Distinguished Professor of Psychiatry and Public Health at the University of California San Diego and Staff Psychiatrist at the Veteran Affairs San Diego Healthcare System, and a consultant to Bionomics.

Additionally, the Company recently held what it believes was a successful, Phase 3-enabling End-of-Phase 2 meeting with the FDA for the advancement of BNC210 for the acute treatment of social anxiety disorder into registrational studies and is awaiting receipt of the formal meeting minutes.

The company will discuss the topline ATTUNE study results on the webcast today at 8:00am EST and is planning to advance BNC210 for the treatment of PTSD into registrational studies.

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 were 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). 212 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 Social Anxiety Disorder (SAD) and PTSD. BNC210 has been given the 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. It should be noted that positive results in or from prior, current, or later clinical trials, studies and pre-clinical development may not provide positive data and/or similar results moving forward, as they are not a predictor or indicative of future results, success or regulatory approval.

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About Bionomics Limited

Bionomics (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 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. 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. 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, 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 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.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/4934b6e5-92ff-4cf7-ba68-2059e9e0a38f