Neurocrine Biosciences Reports Positive Phase 2 Data for NBI-1065845 in Adults with Major Depressive Disorder

April 23, 2024

- ***SAVITRI™ Study Met Primary Endpoint with Statistically Significant Reduction in Montgomery Åsberg Depression Rating Scale (MADRS) Total Score at Day 28***
- ***Met Key Secondary Endpoints, Including Statistically Significant Reduction in MADRS Score at Day 56***
- ***NBI-1065845 Was Generally Well-Tolerated***

SAN DIEGO, April 23, 2024 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX), today announced positive topline data for its Phase 2 SAVITRI™ study. This randomized, double-blind, placebo-controlled dose-finding study assessed the efficacy and safety of NBI-1065845 in adult subjects with major depressive disorder (MDD). NBI-1065845 is an investigational alpha-amino-3-hydroxy-5-methyl-4-isoxazole propionic acid (AMPA) positive allosteric modulator (PAM) in development as a potential treatment for patients with MDD who have not benefited from treatment with at least one antidepressant in their current episode of depression.

The study met its primary and key secondary endpoints, demonstrating that once-daily, oral administration of NBI-1065845 produced a statistically significant change from baseline in Montgomery Åsberg Depression Rating Scale (MADRS) total score at both Day 28 (primary) and Day 56 (secondary). In the full analysis data set, the least squares (LS) mean differences from baseline in MADRS total score for NBI-1065845 were:

- One of the doses demonstrated an improvement over placebo of -4.3 (p-value = 0.0159) and -7.5 (p-value = 0.0016) at Day 28 and Day 56, respectively.
- The other dose also demonstrated a trend toward improvement over placebo of -3.0 (p-value = 0.0873) and -3.6 (p-value = 0.1082) at Day 28 and Day 56, respectively.

NBI-1065845 was generally well tolerated. The most common adverse event was headache. The adverse event profile for both doses of NBI-1065845 were comparable to placebo. There were no deaths or serious adverse events. The discontinuation rates were low throughout the study.

"Many millions of people living with major depressive disorder do not benefit fully from currently available treatments and experience persistent debilitating symptoms," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "NBI-1065845 has the potential to be a first-in-class treatment to alleviate many of these symptoms of MDD. The Phase 2 data from the SAVITRI study are very encouraging, and we look forward to meeting with the FDA to discuss a path into Phase 3 studies."

Additional data from the SAVITRI study will be shared at a future scientific conference.

About the Phase 2 SAVITRI™ Study
The Phase 2 SAVITRI™ study is a double-blind, placebo-controlled study designed to assess the efficacy and safety of investigational NBI-1065845 in adult subjects with major depressive disorder (MDD). The study enrolled 183 adults with a primary diagnosis of MDD and who had inadequate response to current antidepressant treatment.

About NBI-1065845
NBI-1065845 is a potential first-in-class, investigational alpha-amino-3-hydroxy-5-methyl-4-isoxazole propionic acid (AMPA) positive allosteric modulator (PAM) in development as a potential treatment for patients with inadequate response to treatment in MDD.

About the Collaboration with Takeda
In 2020, Neurocrine Biosciences and Takeda (TSE:4502/NYSE:TAK) entered into a strategic collaboration to develop and commercialize compounds in Takeda's early-to-mid-stage psychiatry pipeline, including an exclusive license to NBI-1065845 (TAK-653). Under the terms of the agreement, Neurocrine Biosciences is responsible for developing and commercializing all compounds included in the collaboration and for compounds other than NBI-1065845 and NBI-1065846, Takeda is eligible to receive development or commercial milestone payments and royalties. For NBI-1065845 and NBI-1065846, Takeda may elect to opt out of a 50:50 profit share at certain development events on a program-by-program basis. Until such time Takeda elects to opt out of either profit share arrangement, it will not be eligible to receive development or commercial milestone payments.

About Major Depressive Disorder
Major depressive disorder (MDD) is a mental health disorder characterized by a persistently depressed mood, loss of interest, lack of enjoyment in daily activities, poor concentration, and decreased energy. MDD is one of the leading causes of disability. More than 21 million people in the U.S. live with major depressive disorder. It is estimated that roughly 1/3 of people living with major depressive disorder do not respond to available

antidepressants.

About Neurocrine Biosciences
Neurocrine Biosciences is a leading neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, chorea associated with Huntington's disease, endometriosis* and uterine fibroids*, as well as a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn, X (formerly Twitter), and Facebook.

(**in collaboration with AbbVie)*

Forward-Looking Statement

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements regarding the clinical results from, and our future development plans with respect to, NBI-1065845, as well as the therapeutic potential and clinical benefits or safety profile of NBI-1065845. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements include: top-line data that we report may change following a more comprehensive review of the data related to the clinical studies and such data may not accurately reflect the complete results of the clinical study; risks that regulatory submissions for our products and/or product candidates may not occur or be submitted in a timely manner; our products and/or product candidates may not obtain regulatory approvals; or that the U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions regarding our products and/or product candidates; our products and/or product candidates will not be found to be safe and/or effective or may not prove to be beneficial to patients; that development activities for our products and/or product candidates may not be completed on time or at all; that clinical development activities may be delayed for regulatory or other reasons, may not be successful or replicate previous and/or interim clinical trial results, or may not be predictive of real-world results or of results in subsequent clinical trials; competitive products and technological changes that may limit demand for our products; uncertainties relating to patent protection and intellectual property rights of third parties; our dependence on third parties for development and manufacturing activities related to our products and our product candidates, and our ability to manage these third parties; our future financial and operating performance; risks and uncertainties associated with the commercialization of our products; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's annual report on Form 10-K for the year ended December 31, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

View original content to download multimedia:https://www.prnewswire.com/news-releases/neurocrine-biosciences-reports-positive-phase-2-data-for-nbi-1065845-in-adults-with-major-depressive-disorder-302123889.html

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Inc., Media: Linda Seaton, 1-858-617-7292, media@neurocrine.com; Investors: Todd Tushla, 1-858-617-7143, ir@neurocrine.com