Neurocrine Biosciences Announces First-Patient Dosed in Phase 2 Clinical Study Evaluating NBI-1070770 in Adults with Major Depressive Disorder

April 3, 2024

SAN DIEGO, April 3, 2024 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that the first patient has been randomized for its Phase 2 clinical study to evaluate the efficacy, safety, and tolerability of investigational compound NBI-1070770 in adults with major depressive disorder. NBI-1070770 is a novel, selective, and orally active, negative allosteric modulator (NAM) of the NR2B subunit-containing N-methyl-D-aspartate (NMDA NR2B) receptor.

"Based upon our Phase 1 first-in-human study, we are excited to bring this novel oral compound, which acts through a clinically validated mechanism of action, into clinical development as a potential treatment for major depressive disorder," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "The selectivity of NBI-1070770 for the NMDA NR2B receptor has the potential to benefit patients who have moderate to severe depression."

The NBI-1070770 Phase 2 multi-center, randomized, double-blind, placebo-controlled study will enroll approximately 72 adults and is being conducted at centers throughout the United States. The study will evaluate the safety and efficacy of NBI-1070770 in subjects with major depressive disorder compared to placebo on improving symptoms of depression as measured by the Montgomery-Åsberg Depression Rating Scale. For more information about the Phase 2 study (NBI-1070770-MDD2029), visit Clinicaltrials.gov.

Neurocrine Biosciences acquired the rights to develop and commercialize NBI-1070770 from Takeda Pharmaceutical Company, Ltd.

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 related to the potential benefits of NBI-1070770. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: risks that clinical development activities may not be initiated or completed on time or at all, or may be delayed for regulatory, manufacturing, or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; our future financial and operating performance; risks associated with our dependence on third parties for development, manufacturing, and commercialization activities for our products and product candidates, and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks that the potential benefits of the agreements with our collaboration partners may never be realized; risks that our products, and/or our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks associated with U.S. federal or state legislative or

regulatory and/or policy efforts which may result in, among other things, an adverse impact on our revenues or potential revenue; risks associated with potential generic entrants for 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 other than required by law.

View original content to download multimedia:https://www.prnewswire.com/news-releases/neurocrine-biosciences-announces-first-patient-dosed-in-phase-2-clinical-study-evaluating-nbi-1070770-in-adults-with-major-depressive-disorder-302106187.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