Neurocrine Biosciences Provides Update on Phase 2 Study of NBI-1070770 in Adults with Major Depressive Disorder

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SAN DIEGO, Nov. 10, 2025 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that its Phase 2 study evaluating the efficacy, safety and tolerability of investigational compound NBI-1070770 in adults with major depressive disorder did not meet the primary endpoint compared to placebo. NBI-1070770 was generally well tolerated.

This Phase 2 signal-seeking study enrolled 73 adult patients with a diagnosis of major depressive disorder with inadequate response to at least one antidepressant in their current episode of treatment.

"While we are disappointed that NBI-1070770 did not meet the primary endpoint, there are aspects of the data that warrant further exploration. Our team will continue to analyze these results so we can determine appropriate next steps," said Sanjay Keswani, M.D., Chief Medical Officer, Neurocrine Biosciences. "We are grateful to the patients, investigators and site staff who participated in this trial."

About NBI-1070770

NBI-1070770 is an investigational selective, and orally active, negative allosteric modulator (NAM) of the NR2B subunit-containing N-methyl-D-aspartate (NMDA NR2B) receptor in clinical development as a potential treatment for major depressive disorder.

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

About the NBI-1070770 Phase 2 Clinical Study

The Phase 2, multicenter, randomized, double-blind, placebo-controlled study was designed to evaluate the efficacy, safety and tolerability of three dosage strengths of adjunctive NBI-1070770 compared to placebo (1:1:1:3) on improving symptoms of depression in adults with major depressive disorder who have had an inadequate response to at least one antidepressant. Participants aged 18 to 65 years were randomized to receive either NBI-1070770 or placebo for four weeks during the double-blind treatment period. The primary objective of the study was to assess the change from baseline to Day 5 in depression severity, as measured by the Montgomery-Åsberg Depression Rating Scale (MADRS). For more information about the Phase 2 study, please visit: ClinicalTrials.gov.

About Major Depressive Disorder

Major depressive disorder is a serious disorder characterized by a persistently depressed mood, loss of interest, poor concentration, and decreased energy, among other symptoms. According to the World Health Organization, major depressive disorder is one of the leading causes of disability, is a serious condition that presents an increased risk of suicide and self-harm and is associated with increased all-cause mortality. More than 21 million people in the U.S. live with major depressive disorder, and about half of patients do not get enough relief from their first antidepressant.

About Neurocrine Biosciences, Inc.

Neurocrine Biosciences is a leading neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs. 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, classic congenital adrenal hyperplasia, 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 and Facebook. (**in collaboration with AbbVie*)

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Forward-Looking Statements

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-1070770, as well as the therapeutic potential and clinical benefits or safety profile of NBI-1070770. Factors that could cause actual results to differ materially from those stated or implied in the forward-looking statements include, but are not limited to, the following: top-line data that we report may change following a more comprehensive review of the data related to the clinical study and such data may not accurately reflect the complete results of the clinical study; 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; risks that regulatory submissions for our product candidates may not occur or be submitted in a timely manner; risks and uncertainties associated with Neurocrine Biosciences' business and finances in general; 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 government and third-party regulatory and/or policy efforts which may result in, among other things, an adverse impact on our revenues or potential revenues; risks associated with competition from other therapies or products, including potential generic entrants for our products; risks associated with government and third-party regulatory and/or policy efforts which may, among other things, impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement 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 quarterly report on Form 10-Q for the quarter ended September 30, 2025. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof other than required by law.

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