Neurocrine Biosciences Announces Initiation of Phase 3 Registrational Program for Osavampator as an Adjunctive Therapy for the Treatment of Major Depressive Disorder in Adults

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SAN DIEGO, Jan. 28, 2025 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced the initiation of a Phase 3 registrational study to evaluate the efficacy, safety and tolerability of osavampator (formerly NBI-1065845), an investigational drug under development as an adjunctive treatment to antidepressants for major depressive disorder (MDD). Positive topline data for the Phase 2 SAVITRI™ study of osavampator in adult subjects with MDD were announced in April 2024.

"Osavampator has the potential to become a first-in-class treatment for MDD, a disorder that impacts more than 21 million people in the United States," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "More than a third of those MDD sufferers endure debilitating symptoms that current treatment options cannot fully resolve."

The Phase 2 SAVITRI study with osavampator met its primary and secondary endpoints, and was generally well tolerated.

"Major depressive disorder is a condition that has a profound effect on patients and their families and is associated with significant morbidity and mortality," said Maurizio Fava, M.D., Chair, Mass General Brigham Academic Medical Centers Department of Psychiatry. "The great majority of patients suffering from major depressive disorder do not achieve a sustained remission of their condition and the options for next step strategies to help them are quite limited. This trial is happening at a time when it is clear that, as a field, we need to develop new augmentation strategies to enhance the efficacy of standard antidepressants."

About Osavampator and the Phase 3 Registrational Program

Osavampator (formerly 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. Neurocrine received an exclusive license to osavampator from Takeda Pharmaceutical Company Limited for all indications in all territories worldwide except Japan.

The Phase 3 registrational program is designed to assess the efficacy, safety and tolerability of osavampator in adult subjects with MDD. The study will enroll adults with a primary diagnosis of MDD, who have inadequate response to current antidepressant treatment. For more information about the Phase 3 osavampator study, click here.

About Major Depressive Disorder

Major depressive disorder (MDD) 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, MDD 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 rates. More than 21 million people in the U.S. live with MDD and it is estimated that roughly a third of those 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. 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 (formerly Twitter), and Facebook.

(**in collaboration with AbbVie)*

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 safety, efficacy, and therapeutic potential of NBI-1065845; and the results, conduct, and timing of our NBI-1065845 Phase 3 clinical study. 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: 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; 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 quarterly report on Form 10-Q for the quarter ended September 30, 2024. 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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