Neurocrine Biosciences Announces Amendment to Strategic Collaboration with Takeda to Develop and Commercialize Osavampator (formerly NBI-1065845/TAK-653)

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- *Neurocrine Obtains Exclusive Worldwide Development and Commercialization Rights Excluding Japan and Converts to Royalty-Bearing License for Osavampator*

- *Takeda Reacquires Rights to Osavampator in Japan*

SAN DIEGO, Jan. 27, 2025 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced it has amended its agreement with Takeda to develop and commercialize osavampator (NBI-1065845/TAK-653). Under the amended agreement, Neurocrine will obtain exclusive rights for all indications to develop and commercialize osavampator, a potential first-in-class AMPA positive allosteric modulator in development for patients with inadequate response to treatment of major depressive disorder (MDD) in all territories worldwide except Japan, where Takeda will reacquire exclusive rights. Under the terms of the updated agreement, each company is responsible for development costs in their respective region, and both companies are eligible to receive royalty payments.

"This streamlined collaboration structure allows Neurocrine to focus on bringing this important medicine to patients as quickly as possible," said Kyle Gano, Ph.D., Chief Executive Officer at Neurocrine Biosciences. "With the recent successful completion of our End-of-Phase 2 meeting with FDA for osavampator, we look forward to beginning the Phase 3 program in the first half of this year."

"With its long-standing expertise developing therapies for serious psychiatric disorders, Neurocrine is the ideal partner to develop osavampator," said Sarah Sheikh, M.Sc., B.M., B.Ch, MRCP, Head, Neuroscience Therapeutic Area Unit and Head, Global Development at Takeda. "As it continues to progress through clinical development, osavampator has the potential to add a meaningful new treatment option for patients with MDD."

About the Collaboration with Takeda
In 2020, Neurocrine Biosciences and Takeda entered into a strategic collaboration to develop and commercialize compounds in depression and schizophrenia, including an exclusive license to both osavampator and NBI-1070770, which are being studied for the treatment of major depressive disorder, as well as a preclinical GPR139 antagonist development program.

About Osavampator
Osavampator is a potential first-in-class, investigational alpha-amino-3-hydroxy-5-methyl-4-isoxazole propionic acid (AMPA) positive allosteric modulator (PAM) in development for patients with MDD who have not benefited from treatment with at least one antidepressant in their current episode of depression. In April 2024, Neurocrine announced positive topline data for its Phase 2 SAVITRI™ study in adult subjects with MDD. Neurocrine plans to initiate a Phase 3 program in the first half of this year.

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 related to the benefits to be derived from transactions with Takeda Pharmaceutical Company Limited; statements regarding the clinical results from, and our future development plans with respect to, osavampator, as well as the therapeutic potential and clinical benefits or safety profile of osavampator. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements include: 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; risks that the benefits of the agreements with Takeda may never be realized; 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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