Neurocrine Biosciences Initiates Phase 2 Clinical Study Evaluating NBI-1065890 in Adults with Tardive Dyskinesia

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SAN DIEGO, Jan. 26, 2026 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced the initiation of its Phase 2 clinical study of investigational compound NBI-1065890 in adults with tardive dyskinesia (TD). NBI-1065890 is a next-generation, selective inhibitor of the vesicular monoamine transporter 2 (VMAT2). Building on nearly 20 years of deep scientific expertise and experience in VMAT2 inhibition, Neurocrine designed NBI-1065890 to potentially deliver a differentiated profile, including the possibility of longer-acting options for the treatment of TD.

"NBI-'890 is an internally discovered molecule with distinct physical and chemical properties that may allow it to benefit a broader range of patients with tardive dyskinesia," said Sanjay Keswani, M.D., Chief Medical Officer, Neurocrine Biosciences. "Advancing this program to a Phase 2 clinical study is key to our strategy to define the future of VMAT2 biology and deliver lasting impact for patients."

This Phase 2, randomized, double-blind, placebo-controlled study will enroll approximately 100 adult subjects with TD and will assess the efficacy, safety, and tolerability of NBI-1065890 compared with placebo. The primary efficacy endpoint is change from baseline in the Abnormal Involuntary Movement Scale (AIMS) dyskinesia total score (sum of Items 1–7) at Week 8.

Neurocrine successfully developed and received U.S. Food and Drug Administration approval in 2017 for valbenazine, a selective VMAT2 inhibitor, for use as the first drug ever developed for the treatment of tardive dyskinesia. In 2023, the company received FDA approval for valbenazine as a treatment for chorea associated with Huntington's disease.

For more information about the Phase 2 study (NBI-1065890-TD2033), visit ClinicalTrials.gov.

About Tardive Dyskinesia
Tardive dyskinesia (TD) is a movement disorder that is characterized by uncontrolled, abnormal and repetitive movements of the face, torso and/or other body parts, which may be disruptive and negatively impact patients. The condition is associated with taking certain kinds of mental health medicines (antipsychotics) that help control dopamine receptors in the brain. Taking antipsychotics commonly prescribed to treat mental illnesses such as major depressive disorder, bipolar disorder, schizophrenia and schizoaffective disorder and other prescription medicines (metoclopramide and prochlorperazine) used to treat gastrointestinal disorders are associated with TD. In patients with TD, these treatments are thought to result in irregular dopamine signaling in a region of the brain that controls movement. The symptoms of TD can be mild to severe and are often persistent and irreversible. TD is estimated to affect at least 800,000 adults in the U.S.

About NBI-1065890
NBI-1065890, discovered and developed internally at Neurocrine, is a potent, selective and orally bioavailable inhibitor of vesicular monoamine transporter 2 (VMAT2) in clinical development for the treatment of tardive dyskinesia (TD). Inhibition of VMAT2 is expected to provide therapeutic benefit in TD, other hyperkinetic movement disorders, and potentially other CNS disorders where dopaminergic signaling is dysregulated.

About Neurocrine Biosciences, Inc.
Neurocrine Biosciences is a leading 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, psychiatric, endocrine and immunological 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, Facebook and YouTube. *(*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 efficacy and therapeutic potential of NBI-1065890. 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 annual report on Form 10-K for the year 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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