Neurocrine Biosciences Provides Update on Phase 3 Study of Valbenazine in Dyskinetic Cerebral Palsy

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SAN DIEGO, Dec. 22, 2025 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that its Phase 3 KINECT®-DCP study evaluating the efficacy, safety, and tolerability of valbenazine in pediatric and adult participants who have dyskinetic cerebral palsy (DCP) did not meet primary or key secondary endpoints. The primary objective of the study was to assess improvement in chorea, a type of involuntary movement, in individuals with DCP.

"These results are disappointing, as there are no approved treatments for people living with dyskinetic cerebral palsy," said Sanjay Keswani, M.D., Chief Medical Officer, Neurocrine Biosciences. "We are deeply grateful to the patients and their families, as well as the investigators and site staff, whose commitment, dedication, and participation made this clinical trial possible."

The study – the largest double-blind placebo-controlled clinical trial ever completed in DCP – evaluated the efficacy of 14 weeks of treatment with valbenazine compared with placebo in pediatric and adult participants who have dyskinesia due to cerebral palsy with choreiform movements. Adverse events were generally consistent with the established safety profile for valbenazine.

Neurocrine will report the full study results at an upcoming scientific meeting.

About Dyskinetic Cerebral Palsy
Cerebral palsy (CP) is a nonprogressive neurodevelopmental disorder that affects movement and posture, starting in early childhood. It occurs in about three per 1,000 children in the United States. People living with dyskinetic cerebral palsy (DCP) often have mixed hyperkinetic movements, including dystonia (sustained or intermittent involuntary muscle contractions) and choreoathetosis (random or writhing involuntary movements), leading to severe motor impairment. DCP accounts for approximately 15% of CP cases. Currently, no therapies are approved to treat dystonia or choreoathetosis in CP.

About the Phase 3 KINECT®-DCP Study
The Phase 3, randomized, double-blind, placebo-controlled study was designed to evaluate the efficacy, safety and tolerability of valbenazine for the treatment of dyskinesia due to cerebral palsy in pediatric and adult participants who experience choreiform movements. Participants aged six to 70 years were randomized to receive either valbenazine or placebo for 14 weeks during the double-blind treatment period. Following this, participants had the option to enter an open-label extension phase, during which all received valbenazine. The primary objective for this study is to evaluate the efficacy of valbenazine versus placebo on improving chorea in pediatric and adult subjects who have DCP with choreiform movements.

About Valbenazine
Valbenazine is a selective vesicular monoamine transporter 2 (VMAT2) inhibitor. Neurocrine Biosciences received U.S. Food and Drug Administration approval in 2017 for valbenazine 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. Neurocrine is developing two next generation VMAT2 inhibitors, led by NBI-1065890 entering Phase 2 development for tardive dyskinesia in 2026.

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, 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 clinical results from, and our future development plans with respect to, valbenazine for the treatment of dyskinesia due to cerebral palsy (CP), as well as the therapeutic potential and clinical benefits or safety profile of valbenazine for the treatment of dyskinesia due to CP. 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, including valbenazine for the treatment of dyskinesia due to CP, 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, 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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