Neurocrine Biosciences Announces Topline Data from Phase IIb T-Force GOLD Study Demonstrating Valbenazine Did Not Meet Primary Endpoint in Pediatric Patients with Tourette Syndrome

December 12, 2018

Company to Host Conference Call and Webcast Today at 8:30 a.m. ET / 5:30 a.m. PT

SAN DIEGO, Dec. 12, 2018 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced topline data from the Phase IIb T-Force GOLD study demonstrating that valbenazine did not meet the primary endpoint as assessed by the Yale Global Tic Severity Scale (YGTSS) in children and adolescents with moderate to severe Tourette syndrome. The types of treatment emergent adverse events observed in this trial were consistent with those seen in other valbenazine studies.

"We are very disappointed with the topline data from the T-Force GOLD study given that children and adolescents with Tourette syndrome need better treatment options. This study was well-conducted with a placebo response as expected, but the treatment effect of valbenazine was lower than we had anticipated," said Kevin Gorman, Ph.D., Chief Executive Officer at Neurocrine Biosciences. "We would like to thank the patients, caregivers and investigators for their participation in this study. We will further analyze the data to determine the next steps for valbenazine in Tourette syndrome."

Neurocrine Biosciences continues to focus on developing treatments for neurological and endocrine related disorders. The company discovered, developed and markets INGREZZA® (valbenazine) capsules, the first U.S. Food and Drug Administration (FDA) approved product indicated for the treatment of adults with tardive dyskinesia, an involuntary movement disorder. In addition, as part of a collaboration with AbbVie, ORILISSA™ (elagolix) was approved in 2018 by the FDA for the treatment of endometriosis. Other clinical development programs include opicapone for Parkinson's disease patients, elagolix for uterine fibroids with AbbVie and NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH).

Conference Call and Webcast Today at 8:30 a.m. Eastern Time
Neurocrine will hold a live conference call and webcast today at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time). Participants can access the live conference call by dialing 877-830-2589 (US) or 785-424-1052 (International) using the conference ID: NBIX. The call can also be accessed via the webcast through the Company's website at www.neurocrine.com.

T-Force GOLD Study Design
The T-Force GOLD study was a multicenter, randomized, double-blind, placebo-controlled, parallel group, Phase IIb study to evaluate the safety, tolerability and efficacy of once-daily valbenazine capsules in 127 pediatric patients with moderate to severe Tourette syndrome. Patients received either once-daily dosing of valbenazine or placebo using a 1:1 randomization over 12 weeks of dosing followed by two weeks off-drug. The first six weeks of the trial was a dose optimization phase, with dose escalations allowed at week two or week four. The primary endpoint of T-Force GOLD was the change from baseline of the YGTSS Total Tic Score at week 12. The YGTSS is designed to rate the overall severity of motor and phonic tic symptoms across a range of dimensions: number, frequency, intensity, complexity and interference.

About Tourette Syndrome
Tourette syndrome is a neurological disorder that consists of rapid, non-rhythmic stereotyped motor and vocal tics. Motor tics are typically characterized by facial grimacing, head jerks, extremity movements and other dystonic movements. Vocal tics typically include grunting, throat clearing, and repeating words and phrases. The average age of onset for Tourette syndrome is six years, with symptoms reaching their peak severity at approximately age ten. Tourette syndrome is more commonly diagnosed in males than females and may be associated with attention deficit hyperactivity disorder and obsessive-compulsive disorder as part of a broader spectrum diagnosis.

About INGREZZA® (valbenazine) Capsules
INGREZZA, a selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is the first FDA-approved product indicated for the treatment of adults with tardive dyskinesia, a condition associated with uncontrollable, abnormal and repetitive movements of the face, torso, and/or other body parts.

INGREZZA is thought to work by reducing the amount of dopamine released in a region of the brain that controls movement and motor function, helping to regulate nerve signaling in adults with tardive dyskinesia. VMAT2 is a protein in the brain that packages neurotransmitters, such as dopamine, for transport and release in presynaptic neurons. INGREZZA, developed in Neurocrine's laboratories, is novel in that it selectively inhibits VMAT2 with no appreciable binding affinity for VMAT1, dopaminergic (including D2), serotonergic, adrenergic, histaminergic, or muscarinic receptors. Additionally, INGREZZA can be taken for the treatment of

tardive dyskinesia as one capsule, once-daily, together with psychiatric medications such as antipsychotics or antidepressants.

Important Safety Information

Contraindications
INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

Warnings & Precautions
Somnolence
INGREZZA can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by INGREZZA.

QT Prolongation
INGREZZA may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. INGREZZA should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

Adverse Reactions
The most common adverse reaction (≥5% and twice the rate of placebo) is somnolence. Other adverse reactions (≥2% and >placebo) include: anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at **www.fda.gov/medwatch** or call 1-800-FDA-1088.

Please see INGREZZA full Prescribing Information at www.INGREZZA.com/PI.

About Neurocrine Biosciences, Inc.
Neurocrine Biosciences, a San Diego based biopharmaceutical company, is focused on developing treatments for neurological and endocrine related disorders. The company discovered, developed and markets INGREZZA® (valbenazine) capsules, the first FDA-approved product indicated for the treatment of adults with tardive dyskinesia, an involuntary movement disorder. Discovered and developed through Phase II clinical trials by Neurocrine, ORILISSA™ (elagolix), the first FDA-approved oral medication for the management of endometriosis with associated moderate to severe pain in over a decade, is marketed by AbbVie as part of a collaboration to develop and commercialize elagolix for women's health. Neurocrine's clinical development programs include opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in Parkinson's disease patients, elagolix for uterine fibroids with AbbVie, valbenazine for the treatment of Tourette syndrome, and NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH). For more information and the latest updates from Neurocrine Biosciences, please visit www.neurocrine.com.

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 use of valbenazine in patients with Tourette syndrome, the benefits to be derived from INGREZZA in tardive dyskinesia and the continued success of the launch of INGREZZA in tardive dyskinesia. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: risks that clinical development activities may be delayed for regulatory 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 and uncertainties associated with the commercialization of INGREZZA, including the likelihood of continued revenue and prescription growth of INGREZZA; risks and uncertainties relating to factors that may limit demand for INGREZZA; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA, and the ability of the Company to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding INGREZZA; risks that INGREZZA may be precluded from commercialization or continued commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; 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, 2018. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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