Neurocrine Biosciences to Present New Data Analyses on the Long-Term Effects of INGREZZA® (valbenazine) in Tardive Dyskinesia Patients with Mood Disorders at the 2018 Annual Psych Congress

October 23, 2018

New Data Also Examine the Impact of Uncontrollable Movements as Reported by Patients, Caregivers and Healthcare Providers from RE-KINECT, the Largest Real-World Screening Study of Patients with Possible Tardive Dyskinesia

SAN DIEGO, Oct. 23, 2018 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced it will present new data analyses on the long-term effects of INGREZZA® (valbenazine) capsules in adults with tardive dyskinesia (TD) and from RE-KINECT, the largest real-world screening study of patients with possible TD. INGREZZA is the first U.S. Food and Drug Administration (FDA) approved treatment for adults with TD, a movement disorder that is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face. These new data will be presented at the 2018 Annual Psych Congress in Orlando, Fla., Oct. 25-28, 2018.

"As many patients with tardive dyskinesia are also managing a mood disorder, it is important to provide them with a treatment option that has demonstrated to be effective, is well-tolerated and does not impact the management of their underlying psychiatric condition," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "We look forward to presenting new data analyses on the long-term effects of INGREZZA in patients with tardive dyskinesia who suffer from bipolar disorder, severe depression or other mood disorders and providing further insight on how patients, caregivers and healthcare providers are impacted by their involuntary movements. These data continue to bring additional understanding of the uncontrollable movements caused by tardive dyskinesia and how we can better help patients manage this difficult and burdensome condition."

Poster presentations include new long-term data analyses examining the effects of INGREZZA in adult patients with TD, including: evaluating INGREZZA in TD patients taking concomitant medications for psychiatric conditions; the effects of long-term treatment with INGREZZA in adults with TD and a primary mood disorder; and new data from RE-KINECT on the correlation between uncontrollable movements assessments as reported by patients, caregivers and healthcare providers.

The six Neurocrine-sponsored abstracts that will be presented at the 2018 Annual Psych Congress are:

Poster Presentation Sessions

- **Effects of Long-Term Valbenazine on Psychiatric Status in Patients with Tardive Dyskinesia and a Primary Mood Disorder**
  Abstract 141, Poster Session, Friday, Oct. 26, 1:30-2:30 p.m. ET
- **Tardive Dyskinesia Symptom Screening in Real-World Outpatient Settings: Correlations between Patient-, Caregiver-, and Clinician-Reported Assessments in the RE-KINECT Study**
  Abstract 101, Poster Session, Friday, Oct. 26, 1:30-2:30 p.m. ET
- **Effects of Concomitant Medication Use on Tardive Dyskinesia Outcomes in Long-Term Valbenazine Trials**
  Abstract 224, Poster Session, Friday, Oct. 26, 5:30-7:30 p.m. ET
- **Long-Term Safety and Tolerability of Once-Daily Valbenazine in Patients with Tardive Dyskinesia**
  Abstract 226, Poster Session, Friday, Oct. 26, 1:30-2:30 p.m. ET
- **Valbenazine Treatment of Tardive Dyskinesia in Patients with Intellectual Disability: A Case Series**
  Abstract 114, Poster Session, Friday, Oct. 26, 5:30-7:30 p.m. ET
- **A Modified Delphi Consensus Approach to Clinical Opinions on Tardive Dyskinesia** Abstract 225, Poster Session, Friday, Oct. 26, 1:30-2:30 p.m. ET

About Tardive Dyskinesia (TD)
Tardive dyskinesia (TD) is a movement disorder that is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face. The condition is caused by prolonged use of treatments that block dopamine receptors in the brain, such as antipsychotics commonly prescribed to treat mental illnesses such as schizophrenia, bipolar disorder and depression and certain anti-nausea medications. 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 severe and are often persistent and irreversible. TD is estimated to affect at least 500,000 people in the U.S.

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 trunk, extremities and/or face.

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.INGREZZAHCP.com

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 benefits to be derived from INGREZZA and the continued success of the launch of INGREZZA. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: the Company's future financial and operating performance; 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 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 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 June 30, 2018. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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SOURCE Neurocrine Biosciences, Inc.

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