Neurocrine Announces INGREZZA™ Long-Term Safety and Efficacy Data to be Presented at the 2017 American Academy of Neurology Annual Meeting

April 21, 2017

Additional results from largest ever clinical program in tardive dyskinesia to be highlighted as platform and poster presentations

SAN DIEGO, April 21, 2017 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that long-term safety and efficacy data from the KINECT 3 Phase III extension study of INGREZZA ™(valbenazine) capsules for the treatment of adults with tardive dyskinesia will be presented as a platform presentation at the American Academy of Neurology (AAN) Annual Meeting April 22-28, 2017 in Boston. Additionally, two posters representing additional data from several clinical trials of INGREZZA will be presented, including an analysis of its pharmacologic characteristics.

"We are very pleased to present additional robust data from the largest ever clinical program in tardive dyskinesia at this year's American Academy of Neurology Annual Meeting," said Chris O'Brien, M.D., FAAN, Chief Medical Officer at Neurocrine. "Over 1,000 persons have participated in more than 20 INGREZZA clinical trials, with consistent and strong results demonstrated by the first and only FDA-approved treatment for adults with tardive dyskinesia. These expanded safety, efficacy and pharmacologic findings continue to illustrate INGREZZA's differentiated potential and what it offers to an underserved community."

The two posters presented during Poster Session II on Monday, April 24, 2017 are:

- P2.017: Safety and Tolerability of Valbenazine (NBI-98854) in Subjects with Tardive Dyskinesia: Results of Long-Term Exposure Data from Three Studies
- P2.025: Pharmacologic Characteristics of Valbenazine (NBI-98854) and its Metabolites

The platform presentation during the Movement Disorders: Huntington's Disease and Drug-Induced Dyskinesias Session on Friday, April 28, 2017 (3:30p to 5:30p) at 4:18 pm ET includes:

- S56.005: Efficacy of Valbenazine (NBI-98854) in Subjects with Tardive Dyskinesia: Results of a Long-Term Study (KINECT 3 Extension)

About Tardive Dyskinesia (TD)

TD is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face. The condition is caused by 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

INGREZZA, a selective VMAT2 inhibitor, is the first and only product indicated for the treatment of adults with tardive dyskinesia. The approval of INGREZZA was based on data from the Kinect 3 study, a Phase III, randomized, double-blind, placebo-controlled, parallel-group, fixed-dose study comparing once-daily INGREZZA 80mg and 40mg to placebo over six weeks in patients with underlying schizophrenia, schizoaffective disorder or mood disorder. Subsequent to the completion of the six week placebo-controlled dosing, all eligible subjects were placed on once-daily 40mg or once-daily 80mg of INGREZZA through week 48. INGREZZA met the primary endpoint in this study with a mean change from baseline to week six in the AIMS dyskinesia total score of -3.2 for the 80mg once-daily group as compared to -0.1 in the placebo group ($p < 0.0001$). Also in the Kinect 3 study:

- The percentage of participants who achieved at least a 50% reduction in AIMS was 40.0 percent ($p < 0.001$) in participants receiving 80mg/day of INGREZZA compared to only 8.7 percent of those who received placebo.
- INGREZZA was found to be generally well tolerated, with somnolence as the only adverse event occurring at a rate of 5 percent or greater and twice placebo.

INGREZZA inhibits VMAT2 and 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 TD. 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 together with psychiatric medications such as antipsychotics or antidepressants.

IMPORTANT SAFETY INFORMATION

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 (greater than or equal to 5% and twice the rate of placebo) is somnolence. Other adverse reactions (greater than or equal to 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.

About Neurocrine Biosciences

Neurocrine Biosciences is a San Diego based biotechnology company focused on neurologic, psychiatric and endocrine related disorders. In April of 2017 the FDA approved INGREZZA ™(valbenazine) capsules for the treatment of adults with tardive dyskinesia (TD). INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, and is the first and only FDA-approved product indicated for the treatment of adults with TD. We market INGREZZA in the United States. The Company's three late-stage clinical programs are: elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc.; opicapone, a novel, once-daily, peripherally-acting, highly-selective catechol-o-methyltransferase inhibitor under investigation as adjunct therapy to levodopa in Parkinson's patients; and INGREZZA™ (valbenazine), a novel, once-daily, selective VMAT2 inhibitor under investigation for the treatment of Tourette Syndrome.

Neurocrine Biosciences, Inc. news releases are available through the Company's website at http://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 Neurocrine's products and product candidates, including INGREZZA; the value INGREZZA brings to patients; and whether results from INGREZZA's clinical trials are indicative of real-world results. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: risks and uncertainties associated with Neurocrine's business and finances in general, as well as risks and uncertainties associated with the commercialization of INGREZZA or the development of the Company's product candidates; risks and uncertainties relating to competitive products and technological changes 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 clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that INGREZZA may be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks that the Company will be unable to raise additional funding, if required, to complete development of its product candidates or to commercialize INGREZZA; 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 December 31, 2016. The Company disclaims any obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.

IR@neurocrine.com