Neurocrine Announces INGREZZA® (valbenazine) Capsules Pharmacokinetic Profile and Long-Term Data to be Presented at the 2017 American Psychiatric Association Annual Meeting

May 18, 2017

SAN DIEGO, May 18, 2017 /PRNewswire/ -- Neurocrine Biosciences Inc. (NASDAQ: NBIX) announced today the upcoming presentation at the American Psychiatric Association (APA) Annual Meeting of pharmacokinetic data, as well as long-term data from the KINECT 3 Phase III extension study of INGREZZA® (valbenazine) capsules for the treatment of adults with TD.

"This year's annual meeting of the APA is an excellent opportunity to present additional data and analyses from the extensive clinical development program both supporting and differentiating INGREZZA," said Chris O'Brien, M.D., Chief Medical Officer of Neurocrine. "We are particularly pleased to share this information with Psychiatrists who now have access to the first and only FDA approved treatment for TD patients."

The APA Annual Meeting is May 20-24, 2017, in San Diego, CA. Neurocrine's oral presentation on Saturday, May 20, 2017 in a session from 8:00 a.m. – 11:00 a.m. PT is:

- 3047: New Horizons in Tardive Dyskinesia Research: Valbenazine for Tardive Dyskinesia: Results from Two Randomized, Double-Blind, Placebo-Controlled Trials

The four posters presented during New Research Posters 1 Session on Monday, May 22, 2017 from 10:00 a.m. – 12:00 p.m. PT are:

- 8148: Efficacy of Valbenazine (NBI-98854) in Treating Subjects with Tardive Dyskinesia and Mood Disorder
- 8152: Efficacy of Valbenazine (NBI-98854) in Treating Subjects with Tardive Dyskinesia and Schizophrenia/Schizoaffective Disorder
- 8150: Long-Term Safety and Tolerability of Valbenazine (NBI-98854) in Subjects with Tardive Dyskinesia and a Diagnosis of Schizophrenia or Mood Disorder
- 8082: Single Dose and Repeat Once-Daily Dose Safety, Tolerability and Pharmacokinetics of Valbenazine in Healthy Male Subjects

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 existing stable 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. The company markets 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 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; 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; 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 March 31, 2017. The Company disclaims any obligation to update the statements contained in this press release after the date hereof.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neurocrine-announces-ingrezza-valbenazine-capsules-pharmacokinetic-profile-and-long-term-data-to-be-presented-at-the-2017-american-psychiatric-association-annual-meeting-300460137.html

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