Neurocrine Biosciences Presents Long-term Data Analyses from Open-label KINECT 4 Phase III Study Demonstrating INGREZZA® Improves Tardive Dyskinesia Symptoms

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- INGREZZA (valbenazine) Capsules Taken Once-daily Improved Tardive Dyskinesia Symptoms in Patients and was Generally Well Tolerated in 52-week Trial

- Additional Data Presented from INGREZZA Clinical Studies Show Efficacy Across Adult Patient Groups

SAN DIEGO, Dec. 4, 2017 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced that new long-term data from the KINECT 4 Phase III open-label study demonstrate that once-daily INGREZZA® (valbenazine) capsules, the first FDA approved treatment for adults with tardive dyskinesia (TD), improved TD symptoms through 48 weeks of open-label treatment and was generally well tolerated. TD is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face. These data were presented at the American College of Neuropsychopharmacology (ACNP) Annual Meeting, December 3-7 in Palm Springs, California.

"Neurocrine is committed to helping adult patients with tardive dyskinesia, many of whom are in serious need of treatment to reduce their uncontrollable movements that are often debilitating," said Christopher O'Brien, M.D., Chief Medical Officer of Neurocrine Biosciences. "Consistent with data from previous Phase II/III clinical trials, these new long-term Phase III open-label data will continue to help neurologists and psychiatrists further understand the role of INGREZZA in helping patients who are afflicted with tardive dyskinesia."

In addition to the KINECT 4 Phase III study results, Neurocrine also presented pooled data analyses from three double-blind, placebo-controlled INGREZZA studies (KINECT, KINECT 2 and KINECT 3) across patient sub-groups (219 participants in the ≥55 years of age subgroup and 154 participants in the <55 years of age subgroup). Pooled data analyses showed that once-daily INGREZZA improved tardive dyskinesia symptoms and was generally well tolerated in both older and younger adults.

About the KINECT 4 Phase III Study

Data from the KINECT 4 Phase III study included results from 163 adult patients receiving INGREZZA for long-term treatment of TD which included a 48-week open-label treatment period and a 4-week washout/follow-up period. Across all dose groups, 103 participants who completed the 48-week treatment period experienced clinically meaningful, long-term TD improvement, based on Abnormal Involuntary Movement Scale (AIMS) as assessed by site raters, Clinical Global Impression of Change-TD (CGI-TD) and Patient Global Impression of Change (PGIC) mean scores. Safety assessments included treatment-emergent adverse events (TEAEs). All outcomes were analyzed using descriptive statistics.

About Tardive Dyskinesia (TD)

Tardive dyskinesia (TD) is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face. The condition is associated with 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 may 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

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/HCP

About Neurocrine Biosciences, Inc.
Neurocrine Biosciences is a San Diego based biotechnology company focused on neurologic, psychiatric and endocrine related disorders. The Company markets INGREZZA® (valbenazine) capsules in the United States for the treatment of adults with tardive dyskinesia. INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, and is the first FDA approved product indicated for the treatment of adults with tardive dyskinesia. 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, 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 via the internet 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 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 that INGREZZA clinical trials results may not be predictive of real-world results or of results in subsequent clinical trials; 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 may be alleged to infringe upon 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 September 30, 2017. The Company disclaims any obligation to update the statements contained in this press release after the date hereof.

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