Neurocrine Announces FDA Approval of 80 mg INGREZZA® (valbenazine) Capsules for the Treatment of Adults with Tardive Dyskinesia (TD)

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First and only TD therapy taken as one capsule, once per day; new 80 mg capsule expected to be available for patients within two weeks

INBRACE™ program offers patients access to treatment and patient assistance

SAN DIEGO, Oct. 5, 2017 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that the U.S. Food and Drug Administration (FDA) has approved an 80 mg INGREZZA® (valbenazine) capsule strength to be used for the treatment of adults with tardive dyskinesia (TD). INGREZZA, a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, which was approved by the FDA April 11, 2017, is the first FDA-approved product indicated for the treatment of adults with TD.

"INGREZZA continues to be the TD treatment of choice," said Kevin C. Gorman, Chief Executive Officer of Neurocrine Biosciences. "With the approval of the new 80 mg capsule, patients now have access to an even more convenient treatment option. INGREZZA is the only TD therapy to offer simplified dosing with only one capsule once per day."

Clinical studies have shown that INGREZZA 80 mg provided significant, rapid, and meaningful improvement in TD severity compared to placebo at 6 weeks (-3.2 vs -0.1; P values less than or equal to 0.001) with separation seen as early as two weeks, and continued reductions observed through 48 weeks of treatment. INGREZZA was generally well tolerated, with somnolence as the only adverse event occurring at a rate greater than or equal to 5 percent and twice placebo. In clinical trials, generally no worsening in safety scale scores for depression, suicidal ideation or behaviors was observed. INGREZZA has been studied in over 1,000 individuals and more than 20 clinical trials.

The 80 mg capsule of INGREZZA will be available for patients within two weeks through a select pharmacy network. To assist patients living with TD obtain access to INGREZZA, Neurocrine created the INBRACE™ patient support program, which accepts treatment initiation forms from health care professionals prescribing INGREZZA and works closely with patients and their families to facilitate access. INBRACE is also designed to provide personalized product assistance and services. For more information, patients may visit www.INGREZZA.com or call 1-84-INGREZZA (1-844-647-3992).

About Tardive Dyskinesia (TD)

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

INGREZZA, a selective VMAT2 inhibitor, is the first FDA approved product indicated for the treatment of adults with tardive dyskinesia. 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 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 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 (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. 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; the value INGREZZA brings to patients and caregivers; 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 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 June 30, 2017. The Company disclaims any obligation to update the statements contained in this press release after the date hereof.

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IR@neurocrine.com