



Neurocrine Announces Long-Term Results Evaluating INGREZZA® for the Treatment of Adults with Tardive Dyskinesia Published in the Journal of Clinical Psychiatry

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- Data from the KINECT 3 Phase III Extension Study Show INGREZZA (valbenazine) Maintained Improvement with Favorable Safety Profile in 52-week Trial

SAN DIEGO, Nov. 14, 2017 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that the full manuscript of the long-term safety and efficacy data from the blinded KINECT 3 Phase III extension study evaluating INGREZZA® (valbenazine) capsules for the treatment of adults with tardive dyskinesia (TD) were published in the [Journal of Clinical Psychiatry](#)¹. The once-daily 80 mg and 40 mg doses of INGREZZA continued to maintain symptom improvement and were generally well-tolerated over long-term dosing in patients with TD, a condition characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face.

"We are pleased with the long-term data, which demonstrate the ability of INGREZZA to effectively improve the symptoms of tardive dyskinesia with durable response," said Christopher O'Brien, M.D., Chief Medical Officer of Neurocrine Biosciences. "The data also showed that INGREZZA was generally well-tolerated and did not interfere with the effects of concomitant antipsychotic and antidepressant medications."

Data from the KINECT 3 Phase III extension study included results from 198 patients receiving INGREZZA for long-term treatment of TD. Patients who continued after the initial six-week controlled study period maintained TD improvement as measured by the Abnormal Involuntary Movement Scale (AIMS) and Clinical Global Impression of Change-TD (CGI-TD) through the 42-week INGREZZA double-blind extension period, with scores returning towards baseline after a 4-week INGREZZA washout period. Patients taking INGREZZA showed no apparent risk for suicidal ideation or behavior, nor did INGREZZA appear to induce or worsen akathisia or parkinsonism. Generally, the psychiatric status of patients in the study remained stable during the study.

About the KINECT 3 Phase III Extension Study

Participants who completed the 6-week, double-blind, placebo controlled period of the KINECT 3 Phase III extension study were eligible to enter the 42-week INGREZZA extension period and subsequent 4-week washout period. Participants who received placebo and entered the extension period were re-randomized 1:1 to INGREZZA 40 mg or 80 mg while others continued their KINECT 3 dose in a blinded manner. Safety assessments included treatment-emergent adverse events (TEAEs), scales for suicidal ideation/behavior, treatment-emergent akathisia or parkinsonism, and psychiatric symptoms. Efficacy assessments included the AIMS and CGI-TD scales.

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. INGREZZA is currently in clinical development for the treatment of Tourette syndrome.

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.

References

1. Factor S et al. The Effects of Valbenazine in Participants with Tardive Dyskinesia: Results of the 1-Year KINECT 3 Extension Study *J Clin Psychiatry*; <https://doi.org/10.4088/JCP.17m11777>

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