



Neurocrine to Present Data on the Patient Impact of Tardive Dyskinesia from the RE-KINECT Study at the 2017 Neuroscience Education Institute Congress

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SAN DIEGO, Nov. 7, 2017 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced that data for INGREZZA® (valbenazine) capsules, the first FDA approved treatment for adults with tardive dyskinesia (TD), will be presented at the 2017 Neuroscience Education Institute Congress to be held November 8-12 in Colorado Springs, Colorado. Data being presented include analyses from the RE-KINECT study, a real-world screening study and registry that describes the presence and impact of involuntary movements in patients taking antipsychotics, as well as pooled data analyses from INGREZZA clinical studies across patient sub-groups.

"We are pleased to share findings on the impact of tardive dyskinesia, which is characterized by uncontrollable, abnormal and repetitive movements, on real-world patients," said Chris O'Brien, M.D., Chief Medical Officer of Neurocrine. "With the data from the real-world patient study and further analyses from INGREZZA clinical studies, we have gained valuable insight into the complexities and needs of patients and the effects of INGREZZA on addressing the symptoms of tardive dyskinesia."

Neurocrine's five posters will be presented during the poster sessions on Friday, November 10, 2017 from 5:45 p.m. – 8:00 p.m. MT:

- 117: RE-KINECT: Real-World Dyskinesia Screening Study and Registry in Patients Taking Antipsychotic Agents: Interim Baseline Burden of Illness Results
- 118: Demographics and Real-World Healthcare Utilization for Patients with Probable Tardive Dyskinesia
- 132: Effects of Valbenazine on Depression and Suicidality in Adults with Tardive Dyskinesia: Pooled Results of 3 Double-Blind, Placebo-Controlled Trials
- 141: The Effects of Valbenazine on Tardive Dyskinesia: Subgroup Analyses of 3 Randomized, Double-Blind, Placebo-Controlled Trials
- 150: Estimation of an MCID for AIMS Total Score Change in Tardive Dyskinesia

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 ($\geq 5\%$ and twice the rate of placebo) is somnolence. Other adverse reactions ($\geq 2\%$ 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 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 September 30, 2017. The Company disclaims any obligation to update the statements contained in this press release after the date hereof.

View original content: <http://www.prnewswire.com/news-releases/neurocrine-to-present-data-on-the-patient-impact-of-tardive-dyskinesia-from-the-re-kinect-study-at-the-2017-neuroscience-education-institute-congress-300551247.html>

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Investor Relations, IR@neurocrine.com