



Neurocrine Biosciences to Present Data Analyses Demonstrating the Long-Term Effectiveness of INGREZZA® (valbenazine) in Patients with Tardive Dyskinesia at the 2019 Annual Psych Congress

October 1, 2019

- Data Analyses Evaluate the Long-Term Benefit of INGREZZA® (valbenazine) 40 mg and Early Improvement to Treatment in Patients with Tardive Dyskinesia

- Data from RE-KINECT, the Largest Real-World Screening Study of Patients with Clinician-Confirmed Possible Tardive Dyskinesia, Evaluate Health-Related Quality of Life in Patients with Tardive Dyskinesia

SAN DIEGO, Oct. 1, 2019 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced it will present data analyses evaluating the long-term effects of once-daily 40 mg INGREZZA® (valbenazine) in adults with tardive dyskinesia (TD), an involuntary movement disorder. A data analysis will also be presented on the long-term effects of INGREZZA in patients who demonstrated improvement in TD symptoms as early as two weeks. In addition, Neurocrine Biosciences will present data on the impact possible TD has on a patient's health-related quality of life from RE-KINECT, the largest real-world screening study of patients with clinician-confirmed possible TD. These data will be presented at the 2019 Annual Psych Congress in San Diego, Oct. 3-6, 2019.



"We look forward to presenting data at Psych Congress which will provide further insight into the long-term benefits of INGREZZA for the treatment of tardive dyskinesia, including the effectiveness of the 40 mg dose and the impact of early response to treatment," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "These data provide important clinical information on how INGREZZA can help to manage involuntary movements in patients, and data from our real-world screening study can increase our understanding of the social, physical and emotional impact these movements may have on the everyday lives of patients."

INGREZZA is the first U.S. Food and Drug Administration (FDA) approved treatment for adults with TD, a movement disorder that is characterized by uncontrollable, abnormal and repetitive movements of the face, torso and/or other body parts. The abnormal and involuntary movements of TD can impact patients socially, emotionally and physically, causing patients to feel embarrassed or judged by others or withdraw from society and isolate themselves.

The three Neurocrine-sponsored abstracts that will be presented at the 2019 Annual Psych Congress are:

- **Long-Term Treatment with Valbenazine 40 mg Once-Daily in Adults with Tardive Dyskinesia**
Poster #119, Poster Session, Friday, Oct. 4, 1:30-2:30 p.m. PT
- **Early Response with Valbenazine and Long-Term Symptom Reduction in Patients with Tardive Dyskinesia: Post Hoc Analysis of the KINECT 3 Study**
Poster #133, Poster Session, Friday, Oct. 4, 1:30-2:30 p.m. PT

- **Health-Related Quality of Life in Patients with Possible Tardive Dyskinesia: Results from the Real-World RE-KINECT Study**

Poster #247, Poster Session, Friday, Oct. 4, 1:30-2:30 p.m. PT

About Tardive Dyskinesia (TD)

Tardive dyskinesia (TD) is a movement disorder that is characterized by uncontrollable, abnormal and repetitive movements of the face, torso and/or other body parts, which may be disruptive and negatively impact patients. The condition is caused by prolonged use of 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® (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 face, torso and/or other body parts.

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

Contraindications

INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

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.

Parkinsonism

INGREZZA may cause parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. Reduce the dose or discontinue INGREZZA treatment in patients who develop clinically significant parkinson-like signs or symptoms.

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/PI.

About Neurocrine Biosciences, Inc.

Neurocrine Biosciences (Nasdaq: NBIX) is a neuroscience-focused, biopharmaceutical company with more than 25 years of experience discovering and developing life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia and endometriosis* and clinical development programs in multiple therapeutic areas including Parkinson's disease, congenital adrenal hyperplasia, uterine fibroids* and polycystic ovary syndrome*. Headquartered in San Diego, Neurocrine Biosciences specializes in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. For more information, visit neurocrine.com, and follow the company on [LinkedIn](#). (**in collaboration with AbbVie*)

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 by patients from INGREZZA. 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 the commercialization of 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 clinical development activities may be delayed for regulatory or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that INGREZZA may be precluded from commercialization or continued commercialization by the proprietary or regulatory 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, 2019. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

 View original content to download multimedia: <http://www.prnewswire.com/news-releases/neurocrine-biosciences-to-present-data-analyses-demonstrating-the-long-term-effectiveness-of-ingrezza-valbenazine-in-patients-with-tardive-dyskinesia-at-the-2019-annual-psych-congress-300929123.html>

SOURCE Neurocrine Biosciences, Inc.

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