



## **Neurocrine Biosciences to Present New Quality-of-Life Data Analysis from RE-KINECT, the Largest Real-World Screening Study of Possible Tardive Dyskinesia Patients, at the 2019 American Psychiatric Association Annual Meeting**

May 16, 2019

- **RE-KINECT Analysis Provides Insight into the Impact of Possible Tardive Dyskinesia on Patient Health-Related Quality of Life**
- **New Long-Term Data from the KINECT 4 Study Highlight the Overall Effect of INGREZZA® (valbenazine) Treatment on Abnormal Movements in Patients with Tardive Dyskinesia**

SAN DIEGO, May 16, 2019 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced that it will present a new quality-of-life data analysis from RE-KINECT, the largest real-world screening study of patients with clinician-confirmed possible tardive dyskinesia (TD), an involuntary movement disorder. Neurocrine will also present new long-term data from the KINECT 4 Phase III, open-label study of INGREZZA® (valbenazine) capsules, highlighting the overall effect of treatment with INGREZZA on the abnormal movements associated with TD based on additional items from the Abnormal Involuntary Movement Scale (AIMS), including overall severity of abnormal movements, incapacitation due to abnormal movements and patient awareness of abnormal movements and distress level. These new data analyses will be presented at the American Psychiatric Association (APA) Annual Meeting in San Francisco, May 18-22, 2019.



"We look forward to providing insight at APA from our RE-KINECT study about the impact abnormal movements from possible tardive dyskinesia can have on a patient's quality of life, as well as data on the benefits of long-term treatment with INGREZZA on the overall severity of tardive dyskinesia symptoms," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "Many patients with tardive dyskinesia are impacted socially, emotionally and physically, causing them to feel isolated. Neurocrine Biosciences is committed to further understanding the effect of tardive dyskinesia on patients and the long-term benefits of INGREZZA to help alleviate the symptoms."

INGREZZA is the first U.S. Food and Drug Administration (FDA) approved treatment for adults with TD, an involuntary movement disorder that is characterized by uncontrollable, abnormal and repetitive movements of the face, torso and/or other body parts. TD can be disruptive and negatively impact patients. 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 poster presentations that will be presented at the 2019 APA Annual Meeting are:

- **Health-Related Quality of Life in Patients with Tardive Dyskinesia Based on Patient and Clinician Assessments**  
P7-061, Poster Session 7, Tuesday, May 21, 10:00 a.m.-12:00 p.m. PT
- **Changes in Abnormal Involuntary Movement Scale (AIMS) Items 8, 9, and 10: Results from the Valbenazine KINECT 4 Study**  
P7-044, Poster Session 7, Tuesday, May 21, 10:00 a.m.-12:00 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.

### 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.


Please see INGREZZA full Prescribing Information at [www.INGREZZA.com/PI](http://www.INGREZZA.com/PI).

### About Neurocrine Biosciences

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 and uterine fibroids\*. 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](http://neurocrine.com), and follow the company on [LinkedIn](https://www.linkedin.com/company/neurocrine). (\*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 from Neurocrine's products and product candidates, including INGREZZA; the value INGREZZA and/or our product candidates may bring to patients; the continued success of the launch of INGREZZA; the collaboration with Voyager Therapeutics; and the timing of completion of our clinical, regulatory, and other development activities and those of our collaboration partners. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: risks or uncertainties related to the development of the Company's product candidates; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA or a product candidate; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA and the Company's product candidates, 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, opicapone, or the Company's other product candidates; risks that clinical development activities may not be completed on time or at all; risks that clinical development activities may be delayed for regulatory, manufacturing, 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 the benefits of the agreements with our collaboration partners may never be realized, including Voyager and BIAL; risks that INGREZZA and/or our product candidates may be precluded from 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 March 31, 2019. Neurocrine disclaims any obligation to update the statements contained in this presentation after the date hereof.*

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SOURCE Neurocrine Biosciences, Inc.

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