



## Neurocrine Biosciences to Present New Long-Term Data Analyses on INGREZZA® (valbenazine) at the 2018 International Congress of Parkinson's Disease and Movement Disorders

October 1, 2018

**New Long-Term Data from Phase III KINECT 4 Study Highlights Efficacy of INGREZZA Across Body Regions in Patients with Tardive Dyskinesia**

SAN DIEGO, Oct. 1, 2018 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced it will present new long-term data analyses on INGREZZA® (valbenazine) capsules, the first U.S. Food and Drug Administration (FDA) approved treatment for adults with tardive dyskinesia (TD), at the 2018 International Congress of Parkinson's Disease and Movement Disorders (MDS) in Hong Kong, Oct. 5-9, 2018.



"Neurocrine Biosciences is committed to understanding the severity of movement disorder symptoms in patients living with tardive dyskinesia and to better understand how these symptoms manifest across body regions," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "In our long-term studies with INGREZZA, patients with tardive dyskinesia have shown improvement across body regions, including the face, torso and extremities. We look forward to presenting these new analyses to help healthcare providers further understand how INGREZZA can help patients suffering from tardive dyskinesia."

Poster presentations on INGREZZA include data from three long-term analyses examining the treatment's safety and efficacy over 48 weeks in patients with TD, including the efficacy of INGREZZA by body region, an open-label extension trial reporting on symptom improvement and patient satisfaction with treatment, and the effectiveness of INGREZZA as measured by industry-standard rating scales.

The three Neurocrine-sponsored abstracts that will be presented at the MDS International Congress are:

### Poster Presentation Sessions

- **Effects of Long-Term Valbenazine on Tardive Dyskinesia by Body Region: Shift Analyses of KINECT 4 Study Results**  
Abstract 84, Poster Session: Drug-Induced Movement Disorders, Saturday, Oct. 6, 1:45-3:15 p.m. HKT
- **Assessing the Effectiveness of Valbenazine in the Treatment of Tardive Dyskinesia as Determined by the AIMS and PGIC: Results from the KINECT 4 Trial**  
Abstract 70, Poster Session: Drug-Induced Movement Disorders, Saturday, Oct. 6, 1:45-3:15 p.m. HKT
- **Global Improvement and Patient Satisfaction: Results from a Long-Term, Open-Label, Rollover Study of Valbenazine in Tardive Dyskinesia**  
Abstract 92, Poster Session: Drug-Induced Movement Disorders, Saturday, Oct. 6, 1:45-3:15 p.m. HKT

### About Tardive Dyskinesia (TD)

Tardive dyskinesia (TD) is a movement disorder that is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face. 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 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.

## **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.INGREZZAHCP.com](http://www.INGREZZAHCP.com)


### **About Neurocrine Biosciences, Inc.**

Neurocrine Biosciences, a San Diego based biopharmaceutical company, is focused on developing treatments for neurological and endocrine related disorders. The company discovered, developed and markets INGREZZA<sup>®</sup> (valbenazine) capsules, the first FDA-approved product indicated for the treatment of adults with tardive dyskinesia, a movement disorder. Discovered and developed through Phase II clinical trials by Neurocrine, ORILISSA<sup>™</sup> (elagolix), the first FDA-approved oral medication for the management of endometriosis with associated moderate to severe pain in over a decade, is marketed by AbbVie as part of a collaboration to develop and commercialize elagolix for women's health. Neurocrine's clinical development programs include opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in Parkinson's disease patients, elagolix for uterine fibroids with AbbVie, valbenazine for the treatment of Tourette syndrome, and NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH). For more information and the latest updates from Neurocrine Biosciences, please visit [www.neurocrine.com](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 Neurocrine's products and product candidates; the value our products and/or our product candidates may bring to patients; the continued success of the launch of INGREZZA; the timing of completion of our clinical 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: the Company's future financial and operating performance; risks and uncertainties associated with the commercialization of INGREZZA and ORILISSA, including the likelihood of continued revenue and prescription growth of INGREZZA; risks or uncertainties related to the development of the Company's product candidates, including those with our collaboration partner; risks and uncertainties relating to factors that may limit demand for INGREZZA, ORILISSA, 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, ORILISSA, or the Company's product candidates; risks associated with the Company's dependence on AbbVie for the commercialization of ORILISSA and the development of elagolix; risks that clinical development activities may not be completed on time or at all; 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 associated with the Company's dependence on BIAL for development and manufacturing activities related to opicapone; risks that INGREZZA, ORILISSA, and/or our product candidates 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, 2018. 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-new-long-term-data-analyses-on-ingrezza-valbenazine-at-the-2018-international-congress-of-parkinsons-disease-and-movement-disorders-300722202.html>

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Inc., Navjot Rai (Media & Investors), 858-617-7623, IR@neurocrine.com