



Neurocrine Biosciences to Present Data on INGREZZA® (valbenazine) and Opicapone at the 2019 World Congress on Parkinson's Disease and Related Disorders

June 11, 2019

- INGREZZA Data from Long-Term Phase III Studies Support Sustained Clinical Benefit, Safety and Tolerability in Patients with Tardive Dyskinesia**
- Pooled Analyses of Two Pivotal Studies Showed Opicapone Reduced OFF Time and Was Generally Well Tolerated in More than 500 Patients with Parkinson's Disease and Motor Fluctuations**

SAN DIEGO, June 11, 2019 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced it will present data from two of its movement disorder programs, including INGREZZA® (valbenazine) capsules, the first U.S. Food and Drug Administration (FDA) approved treatment for adults with tardive dyskinesia (TD), and opicapone, an investigational adjunct treatment for Parkinson's disease. Analyses include long-term data on INGREZZA in adult patients with TD, a disorder characterized by uncontrollable, abnormal and repetitive movements of the face, torso and/or other body parts, which may be disruptive and negatively impact patients. In addition, pooled analyses of opicapone will be highlighted, including efficacy data and new safety and tolerability data from two pivotal studies in more than 500 Parkinson's disease patients with motor fluctuations. The data will be presented at the 2019 World Congress on Parkinson's Disease and Related Disorders (IAPRD) in Montreal, June 16-19, 2019.



"We look forward to sharing six clinical presentations from our movement disorder programs, including long-term data showing sustained clinical benefit of INGREZZA in patients with tardive dyskinesia. In addition, we will share Phase III data analyses in Parkinson's disease demonstrating that opicapone was generally well tolerated and prolonged the clinical effect of levodopa, resulting in a significant reduction of OFF time in patients with Parkinson's disease," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "With INGREZZA, it is our goal to provide patients with an effective long-term treatment option to manage the uncontrollable movements of tardive dyskinesia, which can often cause isolation in patients. In patients with Parkinson's disease, we aim to provide a new treatment option to help manage motor fluctuations and better control the effects of this chronic, debilitating disease."

The poster presentations that will be highlighted at the 2019 IAPRD World Congress are:

INGREZZA® (valbenazine)

- The Effects of Valbenazine on Abnormal Involuntary Movement Scale Items 8, 9, and 10: Results from the KINECT 4 Study**
Poster Number: P 206, Topic: Movement Disorders, Monday, June 17, 2019 from 12:45 p.m.-1:45 p.m. ET
- Long-Term Safety and Tolerability of Once-Daily Valbenazine in Patients with Tardive Dyskinesia**
Poster Number: P 203, Topic: Movement Disorders, Tuesday, June 18, 2019 from 12:15 p.m.-1:15 p.m. ET

Opicapone

- Pharmacokinetics of Opicapone and Effect on COMT and Levodopa Pharmacokinetics in Patients with Parkinson's Disease**
Poster Number: P 064, Topic: Parkinson's disease: Clinical science, therapeutics, surgical management, Monday, June 17, 2019 from 12:45 p.m.-1:45 p.m. ET
- Once-Daily Opicapone Increases ON-Time in Patients with Parkinson's Disease: Results from Two Phase 3 Studies**
Poster Number: P 092, Topic: Parkinson's disease: Clinical science, therapeutics, surgical management, Monday, June 17, 2019 from 12:45 p.m.-1:45 p.m. ET
- Symptom Improvements with Once-Daily Opicapone in Patients with Parkinson's Disease and Motor Fluctuations: Pooled Subgroup Analysis of Two Phase 3 Studies**
Poster Number: P 066, Topic: Parkinson's disease: Clinical science, therapeutics, surgical management, Monday, June 17, 2019 from 12:45 p.m.-1:45 p.m. ET
- Safety and Tolerability of Opicapone in Patients with Parkinson's Disease and Motor Fluctuations: Pooled Analysis of Two Phase 3 Studies**
Poster Number: P 063, Topic: Parkinson's disease: Clinical science, therapeutics, surgical management, Tuesday, June 18, 2019 from 12:15 p.m.-1:15 p.m. ET

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 or call 1-800-FDA-1088.

Please see INGREZZA full Prescribing Information at www.INGREZZA.com/PI.

About Parkinson's Disease

Parkinson's disease is a chronic, progressive and debilitating neurodegenerative disorder that affects approximately one million people in the U.S. and six million people worldwide. Parkinson's disease is characterized by a loss of dopamine and its function. Dopamine is a chemical "messenger" that is produced in the brain and is involved in the control of movement. As Parkinson's progresses, dopamine production steadily decreases resulting in slowed movement (bradykinesia), tremor, rigidity, impaired posture and balance, and speech and writing difficulty.

There is no present cure for Parkinson's disease and management consists of controlling the motor symptoms primarily through administration of dopaminergic therapies, including levodopa. While levodopa improves the control of Parkinson's motor symptoms, the disease progresses, and the beneficial effects of levodopa begin to wear off, symptoms worsen and patients experience motor fluctuations.

About Opicapone

Opicapone, an investigational treatment for Parkinson's disease in the U.S., is a novel, once-daily, peripherally-acting, selective catechol-O-methyltransferase (COMT) inhibitor. Opicapone works by prolonging the duration of effect of levodopa through decreasing its conversion rate into 3-O-methyldopa. Discovered in the BIAL – Portela & CA, S.A. (BIAL) laboratories, it is designed to provide patients and physicians with a once-daily option as an adjunct treatment for Parkinson's disease.

In June 2016, the European Commission approved ONGENTYS® (opicapone) as an adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCIs) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilized on those combinations. In February 2017, Neurocrine Biosciences entered into an exclusive licensing agreement with BIAL for the development and commercialization of opicapone in the U.S. and Canada. Opicapone is an investigational drug not approved for use in the U.S. or Canada.

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, 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 from Neurocrine's products and product candidates, including INGREZZA and opicapone; the value INGREZZA and/or opicapone may bring to patients; the continued success of the launch of INGREZZA; the collaboration with BIAL; and the timing of completion of our clinical, regulatory, and other development activities. 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, if approved by the FDA, opicapone; risks associated with the Company's dependence on BIAL and other third parties for development and manufacturing activities related to opicapone and 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 or opicapone; risks that 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 our agreement with BIAL may never be realized; risks that INGREZZA and/or opicapone 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.

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