Neurocrine Biosciences to Present Data from its Movement Disorder Portfolio on the American Academy of Neurology Science Highlights Platform

May 13, 2020

- Data from KINECT 4 Study Provided Additional Long-Term Effectiveness Results in Adult Patients with Tardive Dyskinesia

- New Analysis from Phase III BIPARK-1 Study Evaluate the Efficacy of Once-Daily ONGENTYS® (opicapone) Compared to Entacapone in Patients with Parkinson's Disease

SAN DIEGO, May 13, 2020 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that multiple scientific presentations and abstracts from its movement disorder programs will be available on the 2020 American Academy of Neurology (AAN) Annual Meeting Science Highlights Platform beginning May 18, 2020. Online recorded data presentations and several posters of INGREZZA® (valbenazine) capsules for the treatment of adults with tardive dyskinesia (TD) and ONGENTYS® (opicapone) capsules as an add-on treatment for patients with Parkinson's disease, were selected for the online 2020 AAN Science Highlights Platform which replaced the AAN 72nd annual meeting previously scheduled for April 25–May 1. The abstracts were also published in the online supplement to *Neurology*.

"We look forward to presenting data from our movement disorder programs for tardive dyskinesia and Parkinson's disease at the AAN Science Highlights platform," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "These data provide important clinical information to healthcare providers on the benefits of INGREZZA and ONGENTYS and underscore our commitment to help patients manage these burdensome movement disorders."

The recorded presentations and posters that will be available on the AAN Science Highlights online platform will include:

Tardive Dyskinesia – INGREZZA

- Treatment Responses with Long-Term Valbenazine in Patients with Tardive Dyskinesia [KINECT 4]
- Chart Extraction/Clinician Survey Shows Symptom Impact and Favorable Treatment Outcomes with VMAT2 Inhibitors in Patients with Tardive Dyskinesia
- Effect of Paroxetine on the Pharmacokinetics of Valbenazine and its Active Metabolite

Parkinson's Disease – ONGENTYS

- Efficacy of Opicapone Compared to Entacapone in Parkinson's Patients with Motor Fluctuations and ON Hoehn & Yahr ≤ 2.5: A Post Hoc Analysis of BIPARK-1
- Effect of Once-Daily Opicapone on the Pharmacokinetics of Repaglinide

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 from presynaptic neurons. INGREZZA, developed in Neurocrine Biosciences' 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 (≥5% and twice the rate of placebo) is somnolence. Other adverse reactions (≥2% and >placebo) include: anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia.

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 United States and six million people worldwide. Parkinson's disease is associated with low dopamine levels produced in the brain. Dopamine helps transmit signals between the areas of the brain that control all purposeful movements, including talking, walking and writing. As Parkinson's disease progresses, dopamine production steadily decreases, resulting in increased problems with motor symptoms including slowed movement (bradykinesia), tremor, rigidity, impaired posture and balance, and difficulty with speech and writing.

There is presently no cure for Parkinson's disease and management of the disease consists of the use of treatments that attempt to control motor symptoms primarily through dopaminergic mechanisms. The current gold standard for treatment of motor symptoms is levodopa/carbidopa. While levodopa/carbidopa improves patients' motor symptoms, as the disease progresses, the beneficial effects of levodopa begin to wear off more quickly. Patients then experience motor fluctuations throughout the day between "on" time, periods when the medication is working and Parkinson's disease symptoms are controlled, and "off" time, when the medication is not working and motor symptoms return.

About ONGENTYS® (opicapone) Capsules

ONGENTYS is a novel, once-daily, oral, peripheral, selective and reversible catechol-O-methyltransferase (COMT) inhibitor approved by the U.S. FDA in April 2020 as an add-on treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes. ONGENTYS inhibits the COMT enzyme, which breaks down levodopa, making more levodopa available to reach the brain.

Important Safety Information

Contraindications

ONGENTYS is contraindicated in patients with:

- Concomitant use of non-selective monoamine oxidase (MAO) inhibitors.

- Pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms.

Warnings & Precautions

Cardiovascular Effects with Concomitant Use of Drugs Metabolized by Catechol-O-Methyltransferase (COMT)

Possible arrhythmias, increased heart rate, and excessive changes in blood pressure may occur with concomitant use of ONGENTYS and drugs metabolized by COMT, regardless of the route of administration (including inhalation). Monitor patients treated concomitantly with ONGENTYS and drugs metabolized by COMT.

Falling Asleep During Activities of Daily Living and Somnolence

Patients treated with dopaminergic medications and medications that increase levodopa exposure, including ONGENTYS, have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes has resulted in accidents. If a patient develops daytime sleepiness or somnolence, consider discontinuing ONGENTYS or adjusting other dopaminergic or sedating medications and advise patients to avoid driving and other potentially dangerous activities.

Hypotension/Syncope

Monitor patients for hypotension and advise patients about the risk for syncope. If these adverse reactions occur, consider discontinuing ONGENTYS or adjusting the dosage of other medications that can lower blood pressure.

Dyskinesia

ONGENTYS potentiates the effects of levodopa which may result in dyskinesia or exacerbate pre-existing dyskinesia. Reducing the patient's levodopa dosage or the dosage of another dopaminergic drug may reduce dyskinesia that occurs during treatment with ONGENTYS.

Hallucinations and Psychosis

Consider stopping ONGENTYS if hallucinations or psychotic-like behaviors occur. Patients with a major psychotic disorder should ordinarily not be treated with ONGENTYS.

Impulse Control/Compulsive Disorders

Patients may experience intense urges (e.g., gambling, sexual, spending money, binge eating) and the inability to control them. It is important for prescribers to specifically ask patients or their caregivers about the development of new or increased urges. Re-evaluate the patient's current therapies for Parkinson's disease and consider stopping ONGENTYS if a patient develops such urges while taking ONGENTYS.

Withdrawal-Emergent Hyperpyrexia and Confusion

A symptom complex resembling neuroleptic malignant syndrome (elevated temperature, muscular rigidity, altered consciousness, and autonomic instability), has been reported in association with rapid dose reduction or withdrawal of drugs that increase central dopaminergic tone. There were no reports of neuroleptic malignant syndrome in ONGENTYS controlled clinical studies. When discontinuing ONGENTYS, monitor patients and consider adjustment of other dopaminergic therapies as needed.

Adverse Reactions

The most common adverse reactions (incidence at least 4% and greater than placebo) were dyskinesia, constipation, blood creatine kinase increase, hypotension/syncope, and weight decrease.

Please see ONGENTYS full Prescribing Information at www.neurocrine.com/ongentyspi.

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.

About Neurocrine Biosciences

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with 28 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, Parkinson's disease and endometriosis* and clinical development programs in multiple therapeutic areas including a gene therapy for Parkinson's disease, chorea in Huntington disease, congenital adrenal hyperplasia, epilepsy, 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 from INGREZZA or ONGENTYS; the value INGREZZA or ONGENTYS may bring to patients; and whether clinical trial results from either INGREZZA or ONGENTYS 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 the commercialization of INGREZZA or ONGENTYS; risks that clinical trial activities may not be predictive of real-world results or of results in subsequent clinical trials; risks that INGREZZA or ONGENTYS may be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects or adverse reactions; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA or ONGENTYS; risks associated with the Company's dependence on BIAL for the commercial supply of, and manufacturing activities related to, ONGENTYS, and the ability of the Company to manage BIAL; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; risk and uncertainties related to any COVID-19 quarantines, shelter-in-place and similar government orders that are currently in place or that may be put in place in the future, including the impact of such orders on our business operations and the business operations of the third parties on which we rely; 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, 2020. Neurocrine disclaims any obligation to update the statements contained in this presentation after the date hereof.

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