



Neurocrine Biosciences to Present Data on INGREZZA® (valbenazine) and Opicapone at the 2018 World Congress on Parkinson's Disease and Related Disorders

August 15, 2018

New Long-Term Analyses Highlight Patient-Reported Outcomes and Patient Satisfaction with INGREZZA for the Treatment of Tardive Dyskinesia

Three Analyses from Phase III Study Demonstrate Opicapone Improves Motor Fluctuations in Patients with Parkinson's Disease

SAN DIEGO, Aug. 15, 2018 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced it will present data from its movement disorders programs, including additional long-term results for INGREZZA® (valbenazine) capsules, the first U.S. Food and Drug Administration (FDA) approved treatment for adults with tardive dyskinesia (TD), and data analyses from a Phase III study on opicapone, an investigational treatment for Parkinson's disease. These results will be presented at the 2018 World Congress on Parkinson's Disease and Related Disorders (IAPRD) in Lyon, France, Aug. 19-22, 2018.



"Neurocrine Biosciences is committed to bringing innovative and effective treatments to patients living with movement disorders," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "We look forward to providing additional analyses of INGREZZA's long-term efficacy in tardive dyskinesia, as well as findings from the Phase III BIPARK-I study of opicapone in Parkinson's disease. We believe these results will help healthcare providers further understand the benefits of INGREZZA and the potential of opicapone to help patients suffering from these serious, and often isolating, movement disorders."

Highlighted poster presentations on INGREZZA include data from two long-term studies examining the treatment's safety and efficacy over 48 weeks in patients with tardive dyskinesia, including patient-reported outcome results from the Phase III KINECT 4 study and an open-label, rollover trial reporting on symptom improvement and patient satisfaction with treatment.

Neurocrine will also present three analyses on opicapone from the Phase III BIPARK-I study highlighting the efficacy and safety of once-daily opicapone treatment in patients with Parkinson's disease, compared to placebo and entacapone. Primary outcomes from the BIPARK-I study were previously published in [Lancet Neurology](#), with the outcomes from the open-label extension phase of the BIPARK-I study subsequently published in [Neurology](#).

The five Neurocrine-sponsored abstracts that will be presented at the IAPRD World Congress are:

Oral Presentation Session:

- **Effects of Long-Term Valbenazine on Tardive Dyskinesia and Patient-Reported Outcomes: Results from the KINECT 4 Study**
Abstract OP-02-11, Oral Poster Session II: Ataxias, Tics and/or Myoclonus, Dystonia, Gait and Other Movement Disorders, Tremors, Monday, Aug. 20, 3:45-5:15 p.m. CEST

Poster Presentation Sessions:

- **Global Improvement and Patient Satisfaction: Results from a Long-Term, Open-Label, Rollover Study of Valbenazine in Tardive Dyskinesia**
Abstract P 206, Poster Exhibition: Gait and Other Movement Disorders, Monday, Aug. 20, 12:15-1:15 p.m. CEST
- **Switch of Double-Blind Opicapone, Entacapone, or Placebo to Open-Label Opicapone: Efficacy Results of the 1-Year Extension of Study BIPARK I**
Abstract P 208, Poster Exhibition: Gait and Other Movement Disorders, Monday, Aug. 20, 12:15-1:15 p.m. CEST
- **Efficacy of Opicapone in Parkinson's Disease Patients with Motor Fluctuations: Results from the BIPARK I Study**
Abstract P 207, Poster Exhibition: Gait and Other Movement Disorders, Tuesday, Aug. 21, 12:15-1:15 p.m. CEST
- **Opicapone as Adjunctive Therapy to Levodopa in Patients with Parkinson's Disease and Motor Fluctuations:**

Global Impressions of Change Compared to Placebo and Entacapone

Abstract P 141, Poster Exhibition: Parkinson Disease, Tuesday, Aug. 21, 12:15-1:15 p.m. CEST

About Tardive Dyskinesia (TD)

Tardive dyskinesia (TD) is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face. The condition is caused by 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

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.INGREZZAHCP.com

About Parkinson's Disease

Parkinson's disease is a chronic and progressive movement disorder that affects approximately one million people in the United States. The disease is characterized by a loss of neurons in the substantia nigra, the area of the brain where dopamine is produced. Dopamine production and synthesis is necessary for coordination and movement. As Parkinson's progresses, dopamine production steadily decreases resulting in slowed movement (bradykinesia), tremor, rigidity, impaired posture and balance, and speech and writing problems. There is no present cure for Parkinson's disease and management consists of controlling the motor symptoms primarily through administration of levodopa therapies. While this 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 end-of-dose motor fluctuations. These end-of-dose motor fluctuations can be improved by the addition of a catechol-o-methyltransferase (COMT) inhibitor to levodopa.

About Opicapone

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

In June 2016, the European Commission authorized 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. This European approval was based on data from a clinical development program that included 28 clinical studies of more than 900 patients treated with opicapone in 30 countries worldwide. Opicapone is an investigational drug, not approved for use in the United States or Canada.

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® (valbenazine), 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™ (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.

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 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; risks and uncertainties relating to competitive products and technological changes 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 that the benefits of the agreements with BIAL and Mitsubishi Tanabe may never be realized; risks associated with the Company's dependence on BIAL for tech transfer, development and manufacturing activities related to opicapone; risks associated with the Company's dependence on Mitsubishi Tanabe for the development and commercialization of valbenazine in Japan and other Asian countries; risks that INGREZZA, ORILISSA, 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 June 30, 2018. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

 View original content with multimedia: <http://www.prnewswire.com/news-releases/neurocrine-biosciences-to-present-data-on-ingrezza-valbenazine-and-opicapone-at-the-2018-world-congress-on-parkinsons-disease-and-related-disorders-300697865.html>

SOURCE Neurocrine Biosciences, Inc.

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