Neurocrine Biosciences to Present Data from Movement Disorder Portfolio at the American Academy of Neurology 2022 In-Person and Virtual Annual Meeting

March 24, 2022

SAN DIEGO, March 24, 2022 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that it will present data from its movement disorders program and telemedicine research at the American Academy of Neurology (AAN) Annual Meeting being held in person April 2–7, 2022 in Seattle and virtually April 24–26.

Neurocrine Biosciences will present new findings from a literature review and gap analysis on telemedicine research in serious mental illness and movement disorders. The analysis found that a meaningful evidence gap exists regarding the impact of telemedicine on key outcomes for individuals living with serious mental illness and movement disorders, revealing the need for further research into the benefits and limitations of telemedicine. The company will also present encore data from observational, clinical survey and real-world studies across neurological treatments INGREZZA® (valbenazine) capsules and ONGENTYS® (opicapone) capsules and patient populations.

"The new telemedicine findings we'll be presenting at AAN provide insight into the clinical implications of telemedicine in serious mental illness and movement disorders, which may help to inform how healthcare professionals approach treatment," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "Additionally, the INGREZZA data presentations continue to demonstrate our commitment to deepening our understanding of treatment outcomes in patient populations we serve."

Presentations include:

INGREZZA – Tardive Dyskinesia

- TeleSCOPE: A Real-World Study of Telehealth for the Detection and Treatment of Drug-Induced Movement Disorders (Poster #002 in Neighborhood 11 during Session P1 – Movement Disorders: COVID, Telemedicine and Community)
- Once-Daily Valbenazine is Effective for Tardive Dyskinesia in Elderly Patients (≥65 years) (Poster #004 in Neighborhood 11 during Session P6 – Movement Disorders: Tardive Dyskinesia and PD Imaging)

ONGENTYS – Parkinson's Disease (in collaboration with BIAL)

- Patients' Preferences for Adjunctive Parkinson's Disease Treatments: A Discrete-Choice Experiment (Poster #007 in Neighborhood 11 during Session P11 – Movement Disorders: PD Therapeutics)

Telemedicine

- The Impact of Telemedicine on Serious Mental Illness and Movement Disorders: A Literature Review and Gap Analysis (Poster #003 in Neighborhood 11 during Session P1 – Movement Disorders: COVID, Telemedicine, and Community)

A full list of all abstracts being presented by Neurocrine Biosciences at the 2022 AAN Annual Meeting is available here.

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 associated with taking certain kinds of mental health medicines (like antipsychotics) that help control dopamine receptors in the brain. Antipsychotics commonly prescribed to treat mental illnesses such as depression, bipolar disorder, schizophrenia and schizoaffective disorder, and certain medications to treat upset stomach, nausea and vomiting may also cause TD. 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 approximately 600,000 people in the U.S.

About INGREZZA® (valbenazine) Capsules
INGREZZA, a selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is an 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 by Neurocrine Biosciences, 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 most psychiatric medications such as antipsychotics or antidepressants.

Important Information

Approved Use

INGREZZA® (valbenazine) capsules is a prescription medicine used to treat adults with movements in the face, tongue, or other body parts that cannot be controlled (tardive dyskinesia).

It is not known if INGREZZA is safe and effective in children.

Important Safety Information

Do not take INGREZZA if you:

- are allergic to valbenazine, or any of the ingredients in INGREZZA.

INGREZZA may cause serious side effects, including:

- **Sleepiness (somnolence).** Do not drive, operate heavy machinery, or do other dangerous activities until you know how INGREZZA affects you.
- **Heart rhythm problems (QT prolongation).** INGREZZA may cause a heart problem known as QT prolongation.
- **Symptoms of QT prolongation may include:**
  - fast, slow, or irregular heartbeat
  - shortness of breath
  - dizziness or fainting

  Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you faint.

- Abnormal movements (Parkinson-like). Symptoms include: shaking, body stiffness, trouble moving or walking, or keeping your balance.

Before taking INGREZZA, tell your healthcare provider about all of your medical conditions including if you: have liver or heart problems, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effect of INGREZZA is sleepiness (somnolence). Other side effects include changes in balance (balance problems, dizziness) or an increased risk of falls, headache, feelings of restlessness, dry mouth, constipation, and blurred vision.

These are not all of the possible side effects of INGREZZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
Please see INGREZZA full **Product Information**.

About Parkinson's Disease
Parkinson's disease is a chronic, progressive and debilitating neurodegenerative disorder that affects approximately 1 million people in the U.S. and 6 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 once-daily, oral, peripheral, selective and reversible catechol-O-methyltransferase (COMT) inhibitor approved by the U.S. Food and Drug Administration (FDA) 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.

In June 2016, BIAL – Portela & CA, S.A. (BIAL) received approval from the European Commission for ONGENTYS as an adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilized on those combinations. BIAL currently markets ONGENTYS in several European countries. Neurocrine Biosciences in-licensed opicapone from BIAL in 2017 and has exclusive development and commercialization rights in the U.S. and Canada.

Important Information

Approved Use
ONGENTYS® (opicapone) capsules is a prescription medicine used with levodopa and carbidopa in people with Parkinson's disease (PD) who are having "OFF" episodes.

It is not known if ONGENTYS is safe and effective in children.

Important Safety Information

Do not take ONGENTYS if you:

- take a type of medicine called a non-selective monoamine-oxidase (MAO) inhibitor.
- have a tumor that secretes hormones known as catecholamines.

Before taking ONGENTYS, tell your healthcare provider about all of your medical conditions, including if you:

- have daytime sleepiness from a sleep disorder, have unexpected periods of sleep or sleepiness, or take a medicine to help you sleep or that makes you feel sleepy.
- have had intense urges or unusual behaviors, including gambling, increased sex drive, binge eating, or compulsive shopping.
- have a history of uncontrolled sudden movements (dyskinesia).
- have had hallucinations or psychosis.
- have liver or kidney problems.
- are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take nonselective MAO inhibitors (such as phenelzine, tranylcypromine, and isocarboxazid) or catecholamine medicines (such as isoproterenol, epinephrine, norepinephrine, dopamine, and dobutamine), regardless of how you take the medicine (by mouth, inhaled, or by injection).

ONGENTYS and other medicines may affect each other causing side effects. ONGENTYS may affect the way other medicines work, and other medicines may affect how ONGENTYS works.

What should I avoid while taking ONGENTYS?
Do not drive, operate machinery, or do other dangerous activities until you know how ONGENTYS affects you.

What are the possible side effects of ONGENTYS?
ONGENTYS may cause serious side effects, including:

- **Falling asleep during normal activities** such as driving a car, talking or eating while taking ONGENTYS or other medicines used to treat Parkinson's disease, without being drowsy or without warning. This may result in having accidents. Your chances of falling asleep while taking ONGENTYS are higher if you take other medicines that cause drowsiness.
- **Low blood pressure or dizziness**, light headedness, or fainting.
- **Uncontrolled sudden movements (dyskinesia).** ONGENTYS may cause uncontrolled sudden movements or make such movements worse or happen more often.
- **Seeing, hearing, or feeling things that are not real (hallucinations), believing things that are not real (delusions),** or aggressive behavior.
- **Unusual urges (impulse control and compulsive disorders)** such as urges to gamble, increased sexual urges, strong urges to spend money, binge eating, and the inability to control these urges.

Tell your healthcare provider if you experience any of these side effects or notice changes in your behavior.

The most common side effects of ONGENTYS include uncontrolled sudden movements (dyskinesia), constipation, increase in an enzyme called blood creatine kinase, low blood pressure, and weight loss.

These are not all of the possible side effects of ONGENTYS. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see ONGENTYS full Product Information.

About Chorea associated with Huntington Disease
Huntington disease (HD) is a hereditary progressive, ultimately fatal neurodegenerative disorder in which neurons within the brain break down, resulting in motor, cognitive, and psychiatric symptoms. Symptoms generally appear between the ages of 30 to 50 and worsen over a 10- to 25-year period. Many people with HD experience chorea, a troublesome involuntary movement disorder, characterized by irregular and unpredictable movements. Chorea can affect various body parts and interfere with motor coordination, gait, posture, swallowing, and speech. HD is estimated to affect approximately 41,000 adults in the U.S., with more than 200,000 at risk of inheriting the disease.

About Neurocrine Biosciences
Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis*, and uterine fibroids*, as well as over a dozen mid-to-late-stage clinical programs in multiple therapeutic areas.

For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. 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 regarding the potential benefits to be derived from INGREZZA or ONGENTYS; the value INGREZZA or ONGENTYS may bring to patients; and the outlook of telehealth. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: increased volatility in the telehealth market; inability to adapt to rapid technological changes; 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 and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; 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-K for the year ended December 31, 2021. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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