Neurocrine Biosciences to Present Data from its Neurology Portfolio at the American Academy of Neurology's 73rd 2021 Virtual Meeting

April 8, 2021

SAN DIEGO, April 8, 2021 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that it will present data from its movement disorders and epilepsy programs at the American Academy of Neurology's (AAN) 73rd Annual Meeting being held virtually from April 17–22, 2021.

Key highlights include:

- Analysis from the KINECT 4 Phase III open-label study that demonstrated the effect of INGREZZA® (valbenazine) capsules on the overall severity of abnormal movements in adult patients living with tardive dyskinesia based on item 8 of the abnormal involuntary movement scale (AIMS)
- Phase III post-hoc sub-group data analysis that showed long-term use (one-year duration) of ONGENTYS® (opicapone) capsules in patients with Parkinson's disease with motor fluctuations reduced "on" time with troublesome dyskinesia and increased "on" time without troublesome dyskinesia
- New real-world data from EMPATHY, a retrospective medical chart review, highlight the need to simplify treatment regimens for patients with Parkinson's disease to manage motor fluctuations
- Results of an online caregiver survey include data on the relationship between genetic variants and disease characteristics in patients with SCN8A developmental epileptic encephalopathy (SCN8A-DEE) and SCN8A-related epilepsy
- Data from the Enroll-HD registry, a worldwide observational study, showed that the majority of patients with manifest Huntington disease have chorea, yet the majority of those with chorea were not prescribed medication to treat the condition.

"We are pleased to share important clinical and real-world data that builds on our understanding of neurological conditions with great unmet medical need," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "These data further demonstrate the strength of our broad neurology portfolio and reinforce our commitment to delivering treatments and innovative solutions that have the potential to improve the lives of those living with neurological conditions, including tardive dyskinesia, Parkinson's disease, epilepsy and chorea in Huntington disease."

Presentations include:

INGREZZA – Tardive Dyskinesia

- Using Item 8 of the Abnormal Involuntary Movement Scale (AIMS) to Assess Improvement in Patients with Tardive Dyskinesia (Poster # P14.030)

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

- Long-term Efficacy of Opicapone in the Reduction of ON-time with Troublesome Dyskinesia in Parkinson's Disease Patients with Motor Fluctuations and Reporting Troublesome Dyskinesia (Poster # P14.127)
- Treatment Patterns in a Real-World Sample of Patients with Parkinson's Disease and Motor Fluctuations (Poster # P14.179)
- Medical Education Improves Knowledge Among Neurologists of Newly Approved Pharmacotherapies for the Management of Wearing-Off in Parkinson's Disease (Poster # P14.077)

Investigational NBI-921352/XEN901 – Epilepsy

- Relationship Between Genetic Variants and Disease Characteristics in Patients with SCN8A Developmental and Epileptic Encephalopathy (SCN8A-DEE) or SCN8A-Related Epilepsy (Poster # P7.067)

Chorea in Huntington Disease

- Chorea Characteristics and Medication Use in Patients with Huntington Disease: Current Data from Enroll HD (Poster #

P14.145)

A full list of all abstracts being presented by Neurocrine Biosciences at the 2021 AAN Annual Meeting are 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 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 approximately 600,000 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 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 Safety 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.
- **Parkinson-like symptoms**. Symptoms include: shaking, body stiffness, trouble moving or walking, or keeping your balance.

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

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 caused by 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 NBI-921352/XEN901
NBI-921352 is an investigational, potent, highly selective Nav1.6 sodium channel inhibitor being developed to treat pediatric patients with SCN8A developmental and epileptic encephalopathy (SCN8A-DEE), adult focal epilepsy and other potential indications. Neurocrine Biosciences has received a rare pediatric disease designation from the U.S. FDA for NBI-921352. The company acquired the exclusive rights to NBI-921352 from Xenon Pharmaceuticals.

About SCN8A-DEE
SCN8A developmental and epileptic encephalopathy (SCN8A-DEE), is a rare, severe syndrome linked to gain-of-function mutations in the SCN8A gene that codes for the $Na_V1.6$ sodium channel and affects how brain cells conduct electrical impulses in the brain. It is characterized by severe epilepsy, early onset developmental delay, cognitive impairment and other medical challenges. Seizures associated with this syndrome are highly refractory to currently available antiseizure medication. The seizures, which begin occurring at a median age of four months, can vary in frequency, with some patients experiencing up to several per day. Over 90% of children with SCN8A-DEE are non-verbal, and half are not ambulatory. About 10% of children living with the syndrome die from Sudden Unexpected Death in Epilepsy (SUDEP). There are currently no approved therapies for this form of pediatric epilepsy.

About Chorea in Huntington Disease
Huntington disease (HD) is a hereditary progressive 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 patients with HD experience chorea, a troublesome involuntary movement disorder, in which patients develop abnormal, abrupt or irregular movements. Chorea can affect various body parts and interfere with speech, swallowing, posture and gait. HD is estimated to affect approximately 30,000 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 dedicated to discovering, developing and delivering 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, endometriosis*, uterine fibroids* and clinical programs in multiple therapeutic areas. For nearly three decades, Neurocrine Biosciences has specialized 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 regarding the potential benefits to be derived from the Company's products and product candidates. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements include: the Company's future financial and operating performance; the impact of the COVID-19 pandemic and efforts to mitigate its spread on the Company's business; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local disruptions, the risk that the Company's products or product candidates will not be found to be safe and/or effective or may not prove to be beneficial to patients; that development activities for the Company's product candidates 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 and/or interim clinical trial results, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that regulatory submissions for the Company's product candidates may not occur or be submitted in a timely manner; risks that the Company's product candidates may not obtain regulatory approvals; risks that the potential benefits of the agreements with the Company's collaboration partners may never be realized; risks that the Company's products and/or 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-K for the year ended December 31, 2020. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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