Neurocrine Biosciences to Present New Data Analyses of Once-Daily ONGENTYS® (opicapone) in Patients with Parkinson's Disease at the American Neurological Association 2020 Virtual Meeting

September 28, 2020

- ONGENTYS, the First and Only Once-Daily COMT Inhibitor, Led to Greater Reductions in Overnight "Off" Time and Time to Morning "On" Time Compared to Entacapone When Used as an Add-On Therapy in Patients with Parkinson's Disease with Motor Fluctuations in a Post-Hoc, Sub-Group Analysis of the Phase III, BIPARK-1 Study

- New Phase III Post-Hoc Sub-Group Analysis Demonstrates that Long-Term Treatment with ONGENTYS When Used as an Add-On Therapy Reduced "On" Time with Troublesome Dyskinesia and Increased Good "On" Time Without Troublesome Dyskinesia in Patients with Parkinson's Disease with Motor Fluctuations

SAN DIEGO, Sept. 28, 2020 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced it will present data analyses evaluating the efficacy and safety of ONGENTYS® (opicapone) capsules, recently approved by the U.S. Food and Drug Administration (FDA) as the first and only once-daily catechol-O-methyltransferase (COMT) inhibitor as an add-on to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes. New data from a post-hoc, sub-group analysis of Phase III data showed that ONGENTYS led to greater reductions in overnight "off" time and time to morning "on" time compared to entacapone in patients with Parkinson's disease with motor fluctuations. In another Phase III post-hoc sub-group analysis, long-term use of ONGENTYS in patients with Parkinson's disease with motor fluctuations reduced "on" time with troublesome dyskinesia and increased good "on" time without troublesome dyskinesia. In this analysis, long-term use of ONGENTYS was associated with a reduction in the patient's average daily levodopa dosage requirement. These data will be presented in collaboration with BIAL at the American Neurological Association (ANA) 2020 Virtual Meeting on October 4–9, 2020.

"As Parkinson's disease progresses and the benefit of treatment with levodopa/carbidopa begins to wear off between doses, many patients experience increased fluctuation and unpredictability in their motor function, which can include more 'off' time overnight and during the day, and a reduction in good 'on' time where movement is close to normal," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "These post-hoc analyses from the Phase III clinical trials of ONGENTYS provide further insight on how adding once-daily ONGENTYS to levodopa/carbidopa can help patients with Parkinson's disease better manage disruptive motor fluctuations over the course of the day."

The six ONGENTYS abstracts that will be presented at the ANA 2020 Virtual Meeting are:

- 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 #489)
- Effects of Once-Daily Opicapone on Duration of Overnight OFF and Time to Morning ON in Patients with Parkinson's Disease and Motor Fluctuations (Poster #494)
- Efficacy of Opicapone at Different Levodopa Regimens up to a Threshold of 600 mg/day Levodopa in Parkinson's Disease Patients with Motor Fluctuations (Poster #490)
- Effect of Opicapone and Entacapone on Early Morning-OFF Pattern in Parkinson's Disease Patients with Motor Fluctuations (Poster #477)
- Characterization of the Pattern of Daily Motor Fluctuations in Parkinson's Disease Patients Based on Home Diaries (Poster #493)
- Onset of Drug-Related Adverse Events in Parkinson's Disease Patients with Motor Fluctuations Treated with Opicapone in Clinical Practice: OPTIPARK Post-Hoc Analysis (Poster #485)

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 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 unique, 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 Germany, United Kingdom, Spain, Portugal and Italy. 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 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, endometriosis* and uterine fibroids*, with three pivotal and five mid-stage clinical programs in multiple therapeutic areas. 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 ONGENTYS; and the continued success of the launch of ONGENTYS; our expectations regarding business and financial impacts of the COVID-19 pandemic, including with respect to ONGENTYS availability and the ONGENTYS commercial supply chain and other business operations; and whether results from ONGENTYS's clinical trial results 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 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; risks and uncertainties associated with Neurocrine Biosciences' business and finances in general, as well as risks and uncertainties associated with the commercialization of ONGENTYS; whether ONGENTYS receives adequate reimbursement from third-party payors; the degree and pace of market uptake of ONGENTYS; risks and uncertainties relating to competitive products and technological changes that may limit demand for ONGENTYS; risks that additional regulatory submissions, for ONGENTYS or other product candidates, may not occur or be submitted in a timely manner; risks that the FDA or other regulatory authorities may make adverse decisions regarding ONGENTYS; risks that post-approval ONGENTYS commitments or requirements may be delayed; risks that ONGENTYS may be precluded from commercialization or continued commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks and uncertainties relating to competitive products and technological changes that may limit demand for 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; 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, 2020. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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