Neurocrine Biosciences Presents Real-World Parkinson's Disease Patient Characteristics From ONGENTYS® (opicapone) Open-Label Study at ANA2022

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SAN DIEGO, Oct. 24, 2022 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today presented data detailing the baseline characteristics of patients with Parkinson's disease (PD) in the Opicapone Treatment Initiation Open-Label Study (OPTI-ON). The poster (Poster #M193); Parkinson's Disease Patient Characteristics in a U.S. Real-World Study of Opicapone) was presented at the 2022 American Neurological Association Annual Meeting (ANA2022) being held October 22–25.

"The OPTI-ON study evaluated the use of ONGENTYS® as an adjunct treatment to carbidopa/levodopa in a real-world setting, beginning with consideration of the varied patient types and their existing treatment regimens," said Eiry W. Roberts, MD, Chief Medical Officer at Neurocrine Biosciences. "Full findings from the study will also examine treatment patterns, safety, and tolerability to complement results from the completed pivotal trials."

OPTI-ON is an open-label, single-arm, multicenter, observational, prospective 6-month study of patients with PD experiencing "OFF" episodes who were prescribed ONGENTYS (opicapone) capsules as adjunctive treatment to carbidopa/levodopa (CD/LD). A total of 239 participants across 30 U.S. sites enrolled in the study with a mean PD duration of 8.6 years and a mean (±standard deviation) age of 67.7 (±9.0) years. Patients ranged from "mild" to "advanced" PD severity at baseline, as assessed using the clinician-based PD Status Questionnaire. ONGENTYS was added as an adjunctive treatment to a range of CD/LD regimens, including regimens using extended-release CD/LD capsules.

The full abstract being presented by Neurocrine Biosciences at ANA2022 is available on the meeting website and can be accessed by registering here.

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) 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.

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 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 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, Twitter, and Facebook. (*_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 Neurocrine's products and product candidates. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: our future financial and operating performance; risks associated with the commercialization of ONGENTYS; risks related to the development of our product candidates; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks that our products, 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; risks associated with potential generic entrants for our products; risks associated with our dependence on BIAL for manufacturing activities for ONGENTYS, and our ability to manage BIAL; risks that clinical development activities may not be

completed on time or at all, or may be delayed for regulatory, manufacturing, COVID-19 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 potential benefits of the agreements with our collaboration partners may never be realized; 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 our periodic reports filed with the SEC, including without limitation our quarterly report on Form 10-Q for the quarter ended June 30, 2022. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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