Neurocrine Biosciences Presents Data at MDS International Congress of Parkinson's Disease and Movement Disorders® Demonstrating Comparable Improvement Over Time in Tardive Dyskinesia Severity and Impact Following Treatment With INGREZZA® (valbenazine) Capsules

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SAN DIEGO, Aug. 29, 2023 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today presented findings from a data analysis of KINECT®-4 demonstrating a comparable pattern of improvement over time of clinician-rated tardive dyskinesia (TD) severity and awareness/distress as measured by the Abnormal Involuntary Movement Scale (AIMS) and patient-reported TD impact as measured by the Trajectories of Tardive Dyskinesia Impact Scale (TDIS). The data (Poster #657) was presented at the MDS International Congress of Parkinson's Disease and Movement Disorders® in Copenhagen, Denmark.

The data analysis evaluated the use of INGREZZA for the treatment of TD among all 167 patients with either schizophrenia or mood disorders enrolled over the course of the Phase 3, open-label, long-term study. On average, the analysis suggested that clinician-rated TD severity as measured by AIMS and patient-reported assessment of the physical, social and emotional impact of TD as measured by TDIS decreased with one-capsule, once-daily INGREZZA treatment over the course of the 48-week study. Researchers concluded that the use of AIMS and TDIS in evaluating symptom improvement during treatment may give a more complementary understanding regarding the patient's TD experience.

"The use of AIMS and TDIS provides a more complete perspective on the patient's TD experience," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "While AIMS is helpful to assess TD severity as perceived by the healthcare provider and to follow the severity of TD over time, TDIS enables us to assess the physical, social and emotional impact of these involuntary movements from the patient perspective. The insight gained from these data also supports the efficacy of treatment with INGREZZA in reducing both HCP-perceived severity and patient-reported impact of TD."

The study showed that though AIMS and TDIS measure unique aspects of TD, TDIS demonstrated a comparable pattern of improvement to the AIMS total score, TD severity as measured by AIMS item 8 (AIMS8), incapacitation as measured by AIMS item 9 (AIMS9) and awareness/distress as measured by AIMS item 10 (AIMS10) over the 48-week treatment period.

Key results from the analysis demonstrated the following:

- Mean AIMS total score at baseline was 14.6 and decreased over 48 weeks, with a mean change from baseline of -10.2 (standard deviation [SD]=1.2) for the 40 mg cohort and -11.0 (SD=0.5) for the 80 mg cohort, as assessed by site raters. (n=163)
- At baseline, TD severity was moderate (AIMS8 mean=3.2) and most patients were aware of TD with moderate distress (AIMS10 mean=2.7). TD severity and distress decreased, with most patients scored with minimal severity (AIMS8=1) and as aware/no distress at 48 weeks (AIMS10=1). (n=167)
- Mean TDIS scores decreased from 16.5 at baseline to 6.0 at Week 48, indicating TD had a moderate impact on activity by the end of the INGREZZA treatment period. (n=167)

Additional presentation at the MDS International Congress of Parkinson's Disease and Movement Disorders® includes:

- Crushing Valbenazine Capsule Contents for Potential Addition to Soft Foods or Administration via G Tube (poster #9)

About the KINECT-4 Phase 3 Study

KINECT®-4 is a Phase 3, open-label study, in which 163 participants with moderate to severe TD and underlying schizophrenia, schizoaffective disorder or mood disorder (including bipolar disorder or major depressive disorder) received 48 weeks of open-label treatment with once-daily INGREZZA (40 mg or 80 mg capsules) followed by a four-week washout. Dosing was initiated at 40 mg/day in all participants, with escalation to 80 mg/day at Week 4 based on effectiveness and tolerability. Dose

reduction to 40 mg was allowed in participants who could not tolerate the 80 mg dose. Patients were discontinued if the new dose was not tolerated.

Participants experienced TD improvements during long-term treatment as demonstrated by mean change from baseline to Week 48 in AIMS total score (sum of items 1-7, evaluated by site raters) with INGREZZA 40 mg/day (-10.2) or 80 mg/day (-11.0). Consistent with previous studies, INGREZZA was generally well tolerated. After Week 4, treatment emergent adverse events (TEAEs) that occurred in ≥ 5 percent of all participants (combined dose groups) were urinary tract infection (8.5 percent) and headache (5.2 percent). Changes from baseline in psychiatric stability, vital signs, electrocardiogram parameters and laboratory test values were generally small and not clinically significant.

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. Taking antipsychotics commonly prescribed to treat mental illnesses such as major depressive disorder, bipolar disorder, schizophrenia and schizoaffective disorder, and other prescription medicines (metoclopramide and prochlorperazine) used to treat gastrointestinal disorders are associated with 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 United States.

About INGREZZA® (valbenazine) Capsules
INGREZZA is the only one-capsule, once-daily selective vesicular monoamine transporter 2 (VMAT2) inhibitor approved by the U.S. Food and Drug Administration for the treatment of adults with tardive dyskinesia and the treatment of chorea associated with Huntington's disease (HD).

INGREZZA, developed by Neurocrine Biosciences, selectively inhibits VMAT2 with no appreciable binding affinity for VMAT1, dopaminergic (including D2), serotonergic, adrenergic, histaminergic or muscarinic receptors. While the specific way INGREZZA works to treat HD chorea is not fully understood, INGREZZA selectively targets VMAT2 to inhibit the release of dopamine, a chemical in the brain that helps control movement. INGREZZA is believed to reduce extra dopamine signaling, which may lead to fewer uncontrollable movements. 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. INGREZZA dosages approved for use are 40 mg, 60 mg and 80 mg capsules. INGREZZA is not approved in any other dosage form.

Important Information
Approved Uses

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).
- involuntary movements (chorea) of Huntington's disease. INGREZZA does not cure the cause of involuntary movements, and it does not treat other symptoms of Huntington's disease, such as problems with thinking or emotions.

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

IMPORTANT SAFETY INFORMATION

VMAT2 inhibitors, including INGREZZA, can cause serious side effects in people with Huntington's disease, including: depression, suicidal thoughts, or suicidal actions. Tell your healthcare provider before you start taking INGREZZA if you have Huntington's disease and are depressed (have untreated depression or depression that is not well controlled by medicine) or have suicidal thoughts. Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is especially important when INGREZZA is started and when the dose is changed. Call your healthcare provider right away if you become depressed, have unusual changes in mood or behavior, or have thoughts of hurting yourself.

Do not take INGREZZA if you:

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

INGREZZA may cause serious side effects, including:

- **Sudden swelling from an allergic reaction (angioedema).** Sudden swelling has happened after the first dose or after many doses of INGREZZA. Signs and symptoms of angioedema include: swelling of your face, lips, throat, and other areas of your skin, difficulty swallowing or breathing, and raised, red areas on your skin (hives). Swelling in the throat can be life-threatening and can lead to death. Go to the nearest emergency room right away if you develop these signs and symptoms. Your healthcare provider should stop your treatment with INGREZZA.
- **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, dizziness or fainting, or shortness of breath.

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

- **Neuroleptic Malignant Syndrome (NMS):** NMS is a serious condition that can lead to death. Call a healthcare provider right away or go to the nearest emergency room if you develop these symptoms and they do not have another obvious cause: high fever, stiff muscles, problems thinking, very fast or uneven heartbeat, or increased sweating.
- **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.

Sleepiness (sedation) is a common side effect with INGREZZA. While taking INGREZZA, do not drive a car or operate dangerous machinery until you know how INGREZZA affects you. Drinking alcohol and taking other drugs that may also cause sleepiness while you are taking INGREZZA may increase any sleepiness caused by INGREZZA.

The most common side effect of INGREZZA in people with tardive dyskinesia is sleepiness (somnolence).

The most common side effects of INGREZZA in people with Huntington's disease are sleepiness (somnolence), allergic itching, rash, and trouble getting to sleep or staying asleep.

These are not all of the possible side effects of INGREZZA. Call your doctor for medical advice about side effects. 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, including Boxed Warning.

About Neurocrine Biosciences, Inc.
Neurocrine Biosciences is a leading 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, chorea associated with Huntington's disease, Parkinson's disease, endometriosis* and uterine fibroids*, as well as a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core 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*)

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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 and the value INGREZZA may bring to patients. 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 commercialization of INGREZZA; risks that clinical trial activities may not be predictive of real-world results or of results in subsequent clinical trials; risks that INGREZZA 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; risks associated with our dependence on third parties for development and manufacturing activities related to INGREZZA and our product candidates, and our ability to manage these third parties; 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; 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, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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