Neurocrine Biosciences Reports Patient-Reported Outcome Data from KINECT-PRO™ Study for INGREZZA® (valbenazine) Capsules in Tardive Dyskinesia: Significant and Clinically Meaningful Improvements in Functionality and Quality of Life Measures

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SAN DIEGO, Feb. 27, 2025 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced top-line data from a Phase 4 study, KINECT-PRO™, demonstrating clinically meaningful and sustained effects of INGREZZA® (valbenazine) capsules on the physical, social and emotional impacts experienced by patients living with tardive dyskinesia (TD), irrespective of TD severity or underlying psychiatric condition. KINECT-PRO is the first study to show patient-reported impact of a vesicular monoamine transporter 2 inhibitor, specifically INGREZZA, on TD using multiple clinically validated scales, including the Tardive Dyskinesia Impact Scale used to evaluate the physical, social and emotional impact of involuntary movements. These patient-reported outcome measures provide a more complete perspective on a patient's experience of living with TD and the broad range of improvements that occurred following treatment with INGREZZA. The results of KINECT-PRO will be shared at upcoming scientific conferences.

"Tardive dyskinesia can significantly impact many aspects of patients' lives, including daily activities, work or school attendance and social interactions," said Eiry W. Roberts, M.D., Chief Medical Officer, Neurocrine Biosciences. "The data from the KINECT-PRO trial, which was designed to follow typical clinical practice, show that patients and clinicians observed substantial reduction in the impact and severity of TD, as well as improvement in overall quality of life with use of INGREZZA. Importantly, patients reported significant improvements across measures regardless of their underlying psychiatric conditions or the baseline severity of their TD involuntary movement symptoms."

Fifty-nine patients were enrolled in the KINECT-PRO study and received once-daily INGREZZA (40 mg, 60 mg or 80 mg) for up to 24 weeks. Fifty-two patients completed the Week 24 visit. There were comparable numbers of patients across TD severity (mild vs. moderate/severe) and underlying psychiatric condition subgroups (schizophrenia or schizoaffective disorder vs. bipolar disorder or major depression).

The primary objective of the KINECT-PRO study was to evaluate changes in patient-reported physical and socio-emotional impacts of TD, changes in a person's work, family, social life and overall sense of health and well-being during INGREZZA treatment. These outcomes were measured at Weeks 4, 8, 16 and 24 by the Tardive Dyskinesia Impact Scale (TDIS), the Sheehan Disability Scale (SDS) and the EQ Visual Analogue Scale (EQ-VAS), respectively. The secondary objective was to evaluate clinician- and patient-reported changes in TD severity as measured by the Abnormal Involuntary Movement Scale (AIMS), the Patient Global Impression of Change–TD (PGI-C) and Clinical Global Impression of Severity–TD (CGI-TD-S).

Results showed significant and sustained improvements from baseline in all three patient-reported outcome measures, including patients with either mild or moderate/severe TD, with improvements observed as early as four weeks at the lowest dose (40 mg). AIMS scores also showed sustained reductions in involuntary movements, regardless of TD severity or underlying psychiatric condition. In the study, safety and tolerability of treatment was consistent with the known profile of INGREZZA, with no new concerns identified.

About the KINECT-PRO™ Phase 4 Study

The KINECT-PRO™ Phase 4, open-label study was designed to evaluate patient reported outcomes on the use of INGREZZA® (valbenazine) capsules in a tardive dyskinesia (TD) patient population reflective of real-world clinical practice. Participants had at least mild TD, were aware of and experiencing at least mild distress from their abnormal, involuntary movements and had a clinical diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder or major depression. The KINECT-PRO study included a four-week screening period, a 24-week treatment period during which participants received 40 mg of INGREZZA once-daily for the first four weeks, followed by flexible dosing of 40 mg, 60 mg or 80 mg once-daily based on individual treatment needs and a two-week safety follow-up period. Baseline socio-demographic and clinical characteristics of the participants were broadly similar

to those of the KINECT®-3 and KINECT®-4 studies.

About the Tardive Dyskinesia Impact Scale (TDIS)
The Tardive Dyskinesia Impact Scale (TDIS) is a novel, psychometrically validated patient-reported outcome measure in TD. It was developed by Neurocrine Biosciences from qualitative studies and Phase 3 trials of INGREZZA for the treatment of TD (KINECT®-3 and KINECT®-4) as a comprehensive measure of impact and burden of TD from a patient's perspective. The TDIS consists of 11 questions evaluating physical and socio-emotional impact. Six domains are assessed: mouth/throat, dexterity, mobility, pain, social and emotional. The TDIS allows people with TD to rate how their symptoms affect daily activities and how their uncontrollable movements make them feel. The questionnaire captures relevant information about the impact of TD to provide a more holistic assessment of the condition. Validation of this scale was published in the *Journal of Patient-Reported Outcomes*.

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 (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 at least 800,000 adults in the U.S.

About INGREZZA® (valbenazine) Capsules and INGREZZA® SPRINKLE (valbenazine) Capsules
INGREZZA is a 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). Only INGREZZA offers a therapeutic dose from day one with no required titration.

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 TD and HD chorea is not fully understood, INGREZZA is unique in that it selectively and specifically 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.

INGREZZA is always one capsule, once daily and can be taken together with most stable mental health regimens such as antipsychotics or antidepressants. Only INGREZZA offers the benefit of a sprinkle formulation, INGREZZA® SPRINKLE, for those who experience dysphagia, have difficulty swallowing or prefer not to swallow a pill. INGREZZA and INGREZZA SPRINKLE dosages approved for use are 40 mg, 60 mg and 80 mg capsules.

Important Information

Approved Uses
INGREZZA® (valbenazine) capsules or INGREZZA® SPRINKLE (valbenazine) capsules are prescription medicines 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 or INGREZZA SPRINKLE do not cure the cause of involuntary movements, and do not treat other symptoms of Huntington's disease, such as problems with thinking or emotions.

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

IMPORTANT SAFETY INFORMATION

INGREZZA or INGREZZA SPRINKLE 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 or INGREZZA SPRINKLE 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 or INGREZZA SPRINKLE 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 or INGREZZA SPRINKLE if you:

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

INGREZZA or INGREZZA SPRINKLE can cause serious side effects, including:

- **Allergic reactions.** Allergic reactions, including an allergic reaction that causes sudden swelling called angioedema can happen after taking the first dose or after many doses of INGREZZA or INGREZZA SPRINKLE. Signs and symptoms of allergic reactions and angioedema include: trouble breathing or shortness of breath, swelling of your face, lips, eyelids, tongue, or throat, or other areas of your skin, trouble with swallowing, or rash, including raised, itchy red areas on your skin (hives). Swelling in the throat can be life-threatening and can lead to death. Stop taking INGREZZA or INGREZZA SPRINKLE and go to the nearest emergency room right away if you develop these signs and symptoms of allergic reactions and angioedema.

- **Sleepiness and tiredness that could cause slow reaction times (somnolence and sedation).** Do not drive a car or operate dangerous machinery until you know how INGREZZA or INGREZZA SPRINKLE affects you. Drinking alcohol and taking other medicines may also cause sleepiness during treatment with INGREZZA or INGREZZA SPRINKLE.

- **Heart rhythm problems (QT prolongation).** INGREZZA or INGREZZA SPRINKLE may cause a heart rhythm problem known as QT prolongation. You have a higher chance of getting QT prolongation if you also take certain other medicines during treatment with INGREZZA or INGREZZA SPRINKLE. Tell your healthcare provider right away if you develop any signs or symptoms of QT prolongation, including: fast, slow, or irregular heartbeat (heart palpitations), shortness of breath, dizziness or lightheadedness, or fainting or feeling like you are going to 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, irregular pulse or blood pressure, increased sweating, or very fast or uneven heartbeat.

- **Parkinson-like symptoms.** Symptoms include: body stiffness, drooling, trouble moving or walking, trouble keeping your balance, shaking (tremors), or falls.

Before taking INGREZZA or INGREZZA SPRINKLE, 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. Make sure you tell all of your healthcare providers that you are taking INGREZZA or INGREZZA SPRINKLE. Taking INGREZZA or INGREZZA SPRINKLE with certain other medicines may cause serious side effects. Especially tell your healthcare provider if you: take digoxin or take or have taken a monoamine oxidase inhibitor (MAOI) medicine. You should not take INGREZZA or INGREZZA SPRINKLE if you are taking, or have stopped taking, a MAOI within the last 14 days.

The most common side effects of INGREZZA or INGREZZA SPRINKLE in people with tardive dyskinesia are sleepiness and tiredness.

The most common side effects of INGREZZA or INGREZZA SPRINKLE in people with chorea associated with Huntington's disease include sleepiness and tiredness, raised itchy red areas on your skin (hives), rash, and trouble getting to sleep or staying asleep.

These are not all of the possible side effects of INGREZZA or INGREZZA SPRINKLE. 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.**

Dosage Forms and Strengths: INGREZZA and INGREZZA SPRINKLE are available in 40 mg, 60 mg, and 80 mg capsules.

Please see full Prescribing Information, including Boxed Warning, and Medication Guide.

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. 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, classic congenital adrenal hyperplasia, 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 LinkedIn, X 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 regarding the potential benefits to be derived from INGREZZA and the value INGREZZA may bring to patients. Factors that could cause actual results to differ materially from those stated or implied in the forward-looking statements include, but are not limited to, the following: risks and uncertainties associated with Neurocrine Biosciences' business and finances in general, as well as risks and uncertainties associated with the commercialization of INGREZZA; whether INGREZZA receives adequate reimbursement from third-party payors; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA, and the ability of the Company to manage these third parties; risks that additional regulatory submissions for INGREZZA 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 INGREZZA; risks that post-approval INGREZZA commitments or requirements may be delayed; risks that INGREZZA 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 annual report on Form 10-K for the year ended December 31, 2024. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof other than required by law.

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