Neurocrine Biosciences Announces Publication Establishing Clinically Meaningful Improvement Threshold for the Tardive Dyskinesia Impact Scale

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- Research published in *The Journal of Clinical Psychiatry* characterizes patient-reported improvement with INGREZZA® (valbenazine) capsules across the KINECT® clinical program
- Publication establishes a clinically meaningful improvement threshold for the Tardive Dyskinesia Impact Scale (TDIS™)

SAN DIEGO, April 29, 2026 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced the publication of new peer-reviewed research in *The Journal of Clinical Psychiatry* demonstrating how the Tardive Dyskinesia Impact Scale helps characterize patient-reported burden in tardive dyskinesia and has been used in clinical studies to assess meaningful improvement over the course of treatment with INGREZZA® (valbenazine) capsules.

The article builds on the original validation of the Tardive Dyskinesia Impact Scale (TDIS™) by defining what meaningful improvement means and how TDIS results should be interpreted in clinical trials. Developed in partnership with thought leaders in neurology and psychiatry, TDIS is the first and only psychometrically validated patient-reported outcome measure specifically designed to understand the impact of tardive dyskinesia (TD). It assesses physical and functional impairment, in addition to socio-emotional distress associated with involuntary movements, contributing to a more comprehensive, patient-centered view of the impacts of TD and the benefits of treatment.

"The observable severity of tardive dyskinesia movements does not always reflect the full burden patients endure in their daily lives," said Sanjay Keswani, M.D., Chief Medical Officer, Neurocrine Biosciences. "This publication reinforces the importance of assessing patients' personal experience alongside clinician-rated movement severity to better understand treatment response. It also provides important context for interpreting TDIS results observed in the KINECT clinical program with INGREZZA."

The manuscript establishes a minimal clinically important difference of four points for the TDIS total score, helping define what constitutes clinically meaningful improvement from patient and clinician perspectives. Across the KINECT® 3 and KINECT® 4 studies of INGREZZA, TDIS captured reductions in the physical, social and emotional impact of TD that corresponded with improvements observed in clinician-rated movement severity and global assessments.

The findings also strengthen interpretation of previously reported results from KINECT-PRO™, the first and only clinical study to specifically evaluate and demonstrate patient-reported improvement with INGREZZA on TD using multiple clinically validated scales, including TDIS. Similar to the KINECT-PRO results, these newly published findings showed that patients taking INGREZZA reported robust and clinically meaningful improvements in physical, social and emotional functioning as measured by TDIS.

The complete manuscript, *Measuring What Matters: Further Validation for the Tardive Dyskinesia Impact Scale, a Novel Patient-Reported Outcome Measure in Valbenazine Clinical Trials*, can be viewed here.

About Tardive Dyskinesia
Tardive dyskinesia (TD) is a movement disorder that is characterized by uncontrolled, 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 mild to severe and are often persistent and irreversible. TD is estimated to affect at least 800,000 adults in the U.S.

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.

KINECT-PRO is the first and only study to specifically evaluate and demonstrate patient-reported improvement with vesicular monoamine transporter 2 inhibitor treatment on TD using multiple clinically validated scales, including the Tardive Dyskinesia Impact Scale (TDIS™). The TDIS is the only patient-reported outcome instrument designed for and validated in tardive dyskinesia patients that measures the physical, social and emotional impact of the involuntary movements of the condition.

About the Tardive Dyskinesia Impact Scale

The Tardive Dyskinesia Impact Scale (TDIS ™) is the only patient-reported outcome instrument designed for and validated in tardive dyskinesia patients that measures the physical, social and emotional impact of the involuntary movements of the condition. It was developed by Neurocrine Biosciences in partnership with thought leaders in neurology and psychiatry 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 scales 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 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 studied across the widest range of patients. It 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 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, endocrine, psychiatric and immunological 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 neurocrine.com, and follow the company on LinkedIn, X, Facebook and YouTube. (**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, the interpretation and potential relevance of the data described in this press release, including statements regarding the use and interpretation of the Tardive Dyskinesia Impact Scale (TDIS™), 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 as to whether the data described in this press release will be replicated in additional studies or will be predictive of efficacy or other clinical outcomes in subsequent clinical studies or real-world use of INGREZZA; 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, 2025. 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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