Neurocrine Biosciences Presents Data Adding to the Growing Body of Evidence Demonstrating Functional and Quality of Life Improvements in Patients with Tardive Dyskinesia

May 16, 2025

- Patients Treated with INGREZZA® (valbenazine) Capsules Reported Continued Improvements in Functional and Health-Related Quality of Life Measures
- Findings Presented at 2025 International Society for Pharmacoeconomics and Outcomes Research Conference

SAN DIEGO, May 16, 2025 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced the presentation of new analyses from a Phase 4 randomized withdrawal study (NCT03891862) showing patients with tardive dyskinesia who received continued treatment with INGREZZA® (valbenazine) capsules reported improvements across functional and health-related quality of life measures. These findings complement recently announced patient-reported outcome data from the Phase 4 KINECT-PRO™ studyof INGREZZA, which was the first of its kind to specifically measure and report clinically meaningful improvements in the impact of tardive dyskinesia. The analyses were presented at the 2025 International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Conference in Montreal, Canada.

"Tardive dyskinesia can affect patients' daily lives, causing pain and anxiety and hindering the ability to perform self-care tasks and to participate in work, family or social life," said Eiry W. Roberts, M.D., Chief Medical Officer, Neurocrine Biosciences. "These unique analyses add to the expansive body of evidence demonstrating that INGREZZA treatment can significantly improve tardive dyskinesia patients' quality of life, addressing outcomes important to both patients and healthcare providers."

The analyses were conducted using data from 127 patients who participated in a Phase 4, double-blind, placebo-controlled, randomized withdrawal study. Patients received up to 80 mg of INGREZZA for eight weeks, after which they were randomized to either continue INGREZZA (n=59) or receive placebo (n=59) for an additional eight weeks.

- Health-related quality of life (HRQoL) was measured using the EuroQol 5-Dimension 5-Level (EQ-5D-5L), which includes five dimensions of health status (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). A utility index, ranging from -0.573 to 1.0, and visual analog scale (EQ-VAS), ranging from 0 to 100, were also reported with higher scores indicating better health status.
- Functional impairment was measured using the five-item Sheehan Disability Scale (SDS), in which three items assessed work/school (patient had to be working or attending school to be included), social life and family/home life impairment. Scores were combined for an SDS total score for patients with work/school scores. Reductions in scores indicated improvement.

In the open-label portion of the study, patients receiving INGREZZA treatment for eight weeks experienced significant improvements from baseline in multiple areas of HRQoL (Poster #PCR191), including mobility (change from baseline: -0.27), self-care (-0.28), usual activities (-0.36) and pain/discomfort (-0.34). Those randomized to receive INGREZZA for an additional eight weeks (Week 16) saw continued improvements in all HRQoL dimensions, including significant improvements in mobility (placebo-adjusted difference from Week 8: -0.34) and anxiety/depression (-0.38) compared with those receiving placebo.

In a separate analysis (Poster #PCR190), patients in the open-label portion of the same study receiving INGREZZA treatment for eight weeks experienced significant improvements from baseline in work/school (change from baseline: -1.37), social life (-1.65), family/home life (-1.30) and SDS total score (-4.28). Those randomized to receive INGREZZA for an additional eight weeks saw continued improvements in all domains, including significant improvements in social life (placebo-adjusted difference from Week 8: -0.95) and family/home life (-0.89) compared with those receiving placebo.

Additional presentations at the 2025 ISPOR annual meeting include:

- Assessing Real-World Dosing Patterns for Vesicular Monoamine Transporter-2 Inhibitors, Valbenazine and

Deutetrabenazine, Among Patients with Tardive Dyskinesia in a Nationwide US Claims Database (Poster #HSD80)
- Disparities in Tardive Dyskinesia Diagnosis and Treatment Among the US Medicare Population (Poster #HSD59)
- Disparities in Antipsychotic Prescribing Among the US Medicare Population (Podium Presentation)
- The Impact of Glucocorticoid Dose on Clinical Outcomes in Congenital Adrenal Hyperplasia: a Systematic Literature Review (Poster #CO16)
- Indirect Treatment Comparison for Early Efficacy of VMAT2 Inhibitors for Tardive Dyskinesia and Chorea Associated with Huntington's Disease (Poster #CO113)

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 Chorea Associated with Huntington's Disease
Huntington's disease (HD) is a hereditary progressive neurodegenerative disorder in which the loss of certain neurons within the brain causes motor, cognitive and psychiatric symptoms. Symptoms generally appear between the ages of 30 and 50 years and worsen over a 10- to 25-year period. Most people with HD experience chorea, an abnormal involuntary movement disorder, characterized by irregular and unpredictable movements. Chorea can affect various body parts and interfere with motor coordination, gait, swallowing and speech. HD is estimated to affect approximately 41,000 adults in the U.S., with more than 200,000 at risk of inheriting the disease.

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 proven 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 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 neurocrine.com, and follow the company on 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 quarterly report on Form 10-Q for the quarter ended March 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.

View original content to download multimedia:https://www.prnewswire.com/news-releases/neurocrine-biosciences-presents-data-adding-to-the-growing-body-of-evidence-demonstrating-functional-and-quality-of-life-improvements-in-patients-with-tardive-dyskinesia-302457312.html

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Inc. Media: Aimee White, 1-858-354-7865, media@neurocrine.com; Investors: Todd Tushla, 1-858-617-7143, ir@neurocrine.com