Neurocrine Biosciences Presents New Clinically Meaningful Response Data on Treatment of Tardive Dyskinesia, Reinforcing the Efficacy of INGREZZA® (valbenazine) Capsules Across a Broad Range of Patients

June 8, 2026

- New 48-week KINECT® 4 post-hoc analysis shows 94% of participants treated with INGREZZA achieved either symptomatic remission or a clinically meaningful response (≥30% reduction from baseline in Abnormal Involuntary Movement Scale total score); INGREZZA is the only vesicular monoamine transporter 2 (VMAT2) inhibitor to demonstrate clinical remission in clinical trials
- A separate claims analysis indicates high prevalence of hepatic risk factors among patients with tardive dyskinesia; INGREZZA is the only VMAT2 inhibitor with approved dosing in hepatic impairment
- Together, these data add to a growing body of evidence supporting the potential of INGREZZA to provide clinically meaningful therapeutic benefits to a wide range of patients with tardive dyskinesia

SAN DIEGO, June 8, 2026 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced new post-hoc data from the KINECT® 4 clinical trial demonstrating that adults with tardive dyskinesia (TD) treated with INGREZZA® (valbenazine) capsules experienced clinically meaningful and robust improvements in involuntary movement severity, including those who did not meet the stringent symptomatic remission threshold. These results, together with findings from a large retrospective Medicare claims analysis evaluating hepatic risk factors among patients newly diagnosed with TD, were presented at the 2026 Psych Congress Elevate in Las Vegas.

Previously presented data from the 48-week KINECT 4 study showed that 59% (61/103) of patients treated with once-daily INGREZZA achieved the stringent threshold for TD symptomatic remission, defined as an Abnormal Involuntary Movement Scale (AIMS) item score of 0 ("none") or 1 ("minimal movements") in each of the seven body regions. Symptomatic remission was achieved across TD movement severity subgroups, including 63% (38/60) of patients with moderate TD and 54% (23/43) of patients with severe TD. A new post-hoc analysis further demonstrated that clinically meaningful improvements were observed even among patients who did not meet the more stringent symptomatic remission threshold. Among the 41% of patients (42/103) who did not meet the symptomatic remission threshold at Week 48, 86% (36/42) achieved ≥30% total AIMS score reduction (characterized by the authors as clinically meaningful), and 67% (28/42) achieved ≥50% reduction.

"Treatment goals for tardive dyskinesia include achieving both meaningful reductions in movement severity and, when possible, reaching symptomatic remission, a stringent threshold characterized by absent or minimal involuntary movements across all seven body regions," said Sanjay Keswani, M.D., Chief Medical Officer, Neurocrine Biosciences. "This new analysis demonstrates that approximately 94% of patients treated with INGREZZA for 48 weeks either achieved symptomatic remission or experienced clinically meaningful reductions in their tardive dyskinesia movements. Notably, the benefits of treatment extended beyond patients who reached the stringent remission threshold, reinforcing the broad clinical impact of INGREZZA."

Claims Analysis Underscores Importance of Evaluating Hepatic Risk Factors in TD Treatment Decisions

A separate retrospective Medicare claims analysis of more than 176,000 patients newly diagnosed with TD found that 90% of patients had at least one hepatic risk factor and 44% had three or more. Selected hepatic risk factors included metabolic conditions, such as type 2 diabetes, hypertension, hyperlipidemia and obesity, in addition to substance use-related factors, such as alcohol or drug abuse, are associated with chronic liver disease or hepatic impairment. These findings highlight the importance of evaluating hepatic risk factors when making individualized treatment decisions for TD, as chronic liver disease may progress without noticeable symptoms, and hepatic impairment may go unrecognized, particularly in mild cases. INGREZZA is the only vesicular monoamine transporter 2 inhibitor with approved dosing for patients with TD and coexisting hepatic impairment.

Additional presentations at the 2026 Psych Congress Elevate included:

- Evidence-Based Recommendations for Treating Tardive Dyskinesia with a Vesicular Monoamine Transporter 2 Inhibitor

- Clinically Meaningful Improvements and Symptomatic Remission with Once-Daily Valbenazine in Adults with Tardive Dyskinesia
- Patients Taking Once-Daily Valbenazine Report Improved Quality of Life/Functionality and Experience Remission of Tardive Dyskinesia Symptoms with Once-Daily Valbenazine: Findings From KINECT-PRO
- Once-Daily Valbenazine Demonstrates Greater and More Predictable Exposure Than Deutetrabenazine Extended-Release: Results from a Positron Emission Tomography Study in Healthy Male Adults
- Characterizing Hepatic Risk Factors Among Medicare Patients with Tardive Dyskinesia

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 that occurred in ≥5% of all participants (combined dose groups) were urinary tract infection (8.5%) and headache (5.2%). Changes from baseline in psychiatric stability, vital signs, electrocardiogram parameters and laboratory test values were generally small and not clinically significant.

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 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, developing and commercializing life-changing treatments for patients with under-addressed neurological, psychiatric, endocrine 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, hyperphagia in patients with Prader-Willi syndrome, 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 more than 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 clinically meaningful reductions in involuntary movement severity, symptomatic remission, and hepatic risk factors among patients with tardive dyskinesia, 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 quarterly report on Form 10-Q for the quarter ended March 31, 2026. 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-new-clinically-meaningful-response-data-on-treatment-of-tardive-dyskinesia-reinforcing-the-efficacy-of-ingrezza-valbenazine-capsules-across-a-broad-range-of-patients-302794193.html

SOURCE Neurocrine Biosciences, Inc.

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