Neurocrine Biosciences Announces U.S. FDA Approval of INGREZZA® SPRINKLE (valbenazine) Capsules

April 30, 2024

SAN DIEGO, April 30, 2024 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced the U.S. Food and Drug Administration has approved INGREZZA® SPRINKLE (valbenazine) capsules, a new oral granules formulation of INGREZZA® (valbenazine) capsules prescribed for the treatment of adults with tardive dyskinesia and chorea associated with Huntington's disease.[1] INGREZZA SPRINKLE provides an alternative administration option for those who experience dysphagia or have difficulty swallowing.

Like the original formulation of INGREZZA capsules, INGREZZA SPRINKLE offers simple dosing that's always one capsule, once daily with no complex titration.[1] INGREZZA is the only selective vesicular monoamine transporter 2 (VMAT2) inhibitor that offers three effective dosages (40 mg, 60 mg and 80 mg) that can be adjusted by the healthcare provider based on patient response and tolerability.[1] INGREZZA SPRINKLE offers the same dosage strengths, and the contents of the capsules can be easily sprinkled on soft food for oral administration.

"We developed INGREZZA SPRINKLE to make administration easier for patients who have difficulty swallowing or prefer not to take a capsule," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "We are pleased to offer the proven efficacy of INGREZZA in reducing uncontrollable movements in a new formulation."

Taking pills can be difficult for people experiencing chorea associated with Huntington's disease (HD) in addition to those living with tardive dyskinesia (TD)[2]:

- In a survey of patients with chorea associated with HD and their caregivers (n = 78), 62% reported difficulty swallowing because of their involuntary movements. ‡,†
- In a survey of patients with TD experiencing moderate-to-severe involuntary movement symptoms (n = 250), 37% reported that their movements impacted their ability to eat and drink.*,§

The U.S. Food and Drug Administration (FDA) approval was based on chemistry, manufacturing, and controls information and data demonstrating the bioequivalence and tolerability of INGREZZA SPRINKLE compared to INGREZZA capsules.

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 approximately 600,000 people in the U.S.

About Chorea Associated with Huntington's Disease (HD)
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
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 TD and 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 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 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

VMAT2 inhibitors, including INGREZZA and 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 effect 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 is available in 40 mg, 60 mg, and 80 mg capsules. INGREZZA SPRINKLE is available in 40 mg, 60 mg, and 80 mg oral granules in 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, 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, 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 (formerly Twitter) 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 SPRINKLE and the value INGREZZA SPRINKLE 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 Neurocrine Biosciences' business and finances in general, as well as risks and uncertainties associated with the commercialization of INGREZZA SPRINKLE; whether INGREZZA SPRINKLE receives adequate reimbursement from third-party payors; the degree and pace of market uptake of INGREZZA SPRINKLE; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA SPRINKLE; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA SPRINKLE, and the ability of the Company to manage these third parties; risks that additional regulatory submissions for INGREZZA SPRINKLE 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 SPRINKLE; risks that post-approval INGREZZA SPRINKLE commitments or requirements may be delayed; risks that INGREZZA SPRINKLE may be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA SPRINKLE; 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-K for the year ended December 31, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

References

1. INGREZZA® (valbenazine) capsules (package insert). San Diego, CA; Neurocrine Biosciences. 2024.
2. Date on file. Neurocrine Biosciences, Inc.

*Tardive Dyskinesia Patient ATU 2023. Target patients (diagnosed TD or suspected TD), n = 250.

§Responses based on survey questions: "Since first experiencing involuntary movements, how has your ability to physically perform the following daily activities been affected, if at all?" and "How would you describe the severity of your involuntary movements?" Please use a scale of 1 to 5 when 1 means "Not at all affected" and 5 means "Extremely negatively affected." Results shown include the number of responses greater than or equal to 3 on the scale.

‡ Huntington's Disease Patient and Caregiver ATU 2022. Target patients (patients with chorea seeing an HCP on a regular basis for management of HD and their caregivers), n = 78.

† Responses based on survey question: "Which, if any, of the following involuntary / uncontrollable movement symptoms [PATIENT have] [CAREGIVER has] you ever experienced (or someone else has noticed [PATIENT you] [CAREGIVER they] experienced)? This includes symptoms that may be controlled by medication. Please select all that apply."

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