



Neurocrine Biosciences Announces FDA Approval of INGREZZA® (valbenazine) Capsules for the Treatment of Chorea Associated With Huntington's Disease

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SAN DIEGO, Aug. 18, 2023 /PRNewswire/ -- [Neurocrine Biosciences, Inc.](#) (Nasdaq: NBIX) today announced the U.S. Food and Drug Administration (FDA) has approved INGREZZA® (valbenazine) capsules for the treatment of adults with chorea associated with Huntington's disease (HD).¹ INGREZZA is the only selective vesicular monoamine transporter 2 (VMAT2) inhibitor that offers an effective starting dosage that can be adjusted by a patient's healthcare provider based on response and tolerability, with no complex titration.¹ Only INGREZZA offers simple dosing that is always one capsule, once daily.¹

Experience the full interactive Multichannel News Release here: <https://www.multivu.com/players/English/9147451-neurocrine-biosciences-fda-approval-ingrezza/>

The FDA approval is supported by data from two clinical studies conducted in collaboration with the Huntington Study Group (HSG), including the KINECT®-HD Phase 3 study and the ongoing KINECT®-HD2 open-label extension trial.^{1,2} KINECT-HD, a randomized, double-blind, placebo-controlled study that evaluated the efficacy and safety of INGREZZA, met its primary endpoint of least squares mean (LSM) change in chorea severity using the Total Maximal Chorea (TMC) score of the Unified Huntington's Disease Rating Scale (UHDRS) from screening period baseline to maintenance period (average of Weeks 10 and 12), demonstrating a statistically significant greater improvement in TMC score with INGREZZA versus placebo.^{1,2}

"We are proud to bring INGREZZA to people living with HD and their caregivers who now have the option of a one-capsule, once-daily treatment that has demonstrated significant improvement in HD chorea in clinical studies," said Kevin C. Gorman, Chief Executive Officer, Neurocrine Biosciences. "We are thankful for those in the HD community who helped contribute to this important milestone, and we remain committed to bringing medicines to patients with unmet medical needs for debilitating neurological disorders."

Key clinical trial outcomes from KINECT-HD include:

- INGREZZA demonstrated a three-times greater improvement in chorea severity compared to placebo, with a 4.6-point improvement seen with INGREZZA versus a 1.4-point improvement with placebo in the chorea severity score from the start to the end of the 12-week clinical study (least squares mean difference -3.2, 95% CI, -4.4 to -2.0; $P < 0.0001$).^{1,2}
- INGREZZA reduced chorea severity by about 40 percent from baseline to maintenance ($P < 0.0001$) and nearly half of patients saw a more than 40 percent reduction in HD chorea severity by Week 12.^{1,2}
- Fifty-three percent of patients and 43 percent of healthcare professionals reported overall HD chorea symptoms were "very much improved" or "much improved" at Week 12.^{1,2}

Like other FDA-approved treatments for chorea associated with HD, the prescribing information for INGREZZA now includes important safety information regarding serious risk, including depression and suicidal ideation and behavior in patients with Huntington's disease and Neuroleptic Malignant Syndrome (NMS).

In clinical studies in Huntington's disease, treatment-emergent adverse events included somnolence and sedation, urticaria, rash and insomnia.

See full Important Safety Information below.

"Clinical results that led to this important approval showed reduction in the severity of chorea as early as two weeks after starting INGREZZA at an initial dose of 40 mg, with consistently greater improvements versus placebo seen at all subsequent visits," said Erin Furr Stimming, M.D., FAAN, FANA, Principal Investigator, Huntington Study Group and Professor of Neurology, McGovern Medical, UTHealth Houston. "Data also demonstrated INGREZZA was generally well tolerated and showed clinically meaningful improvement in adults with chorea associated with HD."

"Chorea associated with HD can significantly affect the quality of life of a person living with HD by impacting their daily activities, social life, independence and overall well-being," said Louise Vetter, President and Chief Executive Officer of the Huntington's Disease Society of America. "The approval of INGREZZA for HD chorea means that people living with HD have a new treatment option to help manage their chorea symptoms, which is a welcomed milestone in efforts to improve care for families affected by

HD."

The INBRACE® Support Program helps patients who are prescribed INGREZZA by assisting with product support and prescription fulfillment through a dedicated network of carefully selected specialty and local affiliated pharmacies. Patients with commercial insurance may be eligible for copay assistance and patients with no prescription coverage who also lack the financial resources to pay for their medicine may be eligible for participation in the patient assistance program. For more information, patients may visit INBRACESupportProgram.com/INGREZZAPatient/.

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 the KINECT®-HD Study

KINECT®-HD is a Phase 3, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy of valbenazine as a once-daily treatment to reduce chorea associated with Huntington's disease (HD) and evaluate the safety and tolerability of valbenazine in patients with HD. The study enrolled 128 adults 18 to 75 years of age who were diagnosed with motor-manifest HD and who had sufficient chorea symptoms to meet study protocol criteria.

KINECT-HD used the Unified Huntington's Disease Rating Scale (UHDRS) Total Maximal Chorea (TMC) score as the primary efficacy endpoint. The secondary endpoints included Clinical Global Impression of Change (CGI-C) response status and Patient Global Impression of Change (PGI-C) response status for valbenazine treatment. Treatment with valbenazine resulted in a placebo-adjusted mean reduction in the TMC score of 3.2 units ($P < 0.0001$), indicating a highly statistically significant improvement in chorea. Secondary endpoints of CGI-C response status and PGI-C response status were also statistically significant and supported the improvements in TMC score that were seen over the 12-week study period.

Treatment-emergent adverse events in this study were generally consistent with the known safety profile of valbenazine. No suicidal behavior or worsening of suicidal ideation were observed in the valbenazine-treated participants in this study.

View the complete study results from the Phase 3 KINECT-HD study published in *The Lancet Neurology* [online edition](#). For more information on the KINECT-HD study, please visit HuntingtonStudyGroup.org.

About KINECT®-HD2

KINECT®-HD2 is an ongoing open-label study to evaluate the long-term safety and tolerability, as well as the maintenance of effects, of INGREZZA in patients with chorea associated with Huntington's disease (HD). The 156-week study will enroll more than 150 adults 18 to 75 years of age who have been diagnosed with motor-manifest HD and who have sufficient chorea symptoms to meet study protocol criteria. Concomitant antipsychotic use is allowed in the study. For more information on the KINECT-HD2 study, please visit HuntingtonStudyGroup.org or ClinicalTrials.gov.

About Huntington Study Group/HSG Clinical Research, Inc.

The Huntington Study Group (HSG), a not-for-profit organization founded in 1993 in Rochester, NY, and its wholly owned subsidiary, HSG Clinical Research, Inc., designs and conducts clinical trials through the world's first and largest collaborative network with thousands of members at more than 130 HSG credentialed research sites worldwide. HSG is dedicated to improving the lives of people impacted by Huntington's disease through research, education, and collaboration. For more information, visit HuntingtonStudyGroup.org.

The KINECT-HD study was conducted in cooperation with the HSG and the Clinical Trials Coordination Center (CTCC) at the University of Rochester Medical Center's Center for Health + Technology (CHeT). For more information, visit urmc.Rochester.edu/Health-Technology/Our-Expertise/Clinical-Trials-Coordination.aspx.

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 for the treatment of tardive dyskinesia 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 is a prescription medicine 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 does not cure the cause of involuntary movements, and it does not treat other symptoms of Huntington's disease, such as problems with thinking or emotions.

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

IMPORTANT SAFETY INFORMATION

VMAT2 inhibitors, including INGREZZA, 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 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 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 if you:

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

INGREZZA may cause serious side effects, including:

- **Sudden swelling from an allergic reaction (angioedema).** Sudden swelling has happened after the first dose or after many doses of INGREZZA. Signs and symptoms of angioedema include: swelling of your face, lips, throat, and other areas of your skin, difficulty swallowing or breathing, and raised, red areas on your skin (hives). Swelling in the throat can be life-threatening and can lead to death. Go to the nearest emergency room right away if you develop these signs and symptoms. Your healthcare provider should stop your treatment with INGREZZA.
- **Heart rhythm problems (QT prolongation).** INGREZZA may cause a heart problem known as QT prolongation. **Symptoms of QT prolongation may include:** fast, slow, or irregular heartbeat, dizziness or fainting, or shortness of breath.

Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you 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, very fast or uneven heartbeat, or increased sweating.
- **Abnormal movements (Parkinson-like).** Symptoms include: shaking, body stiffness, trouble moving or walking, or keeping your balance.

Before taking INGREZZA, 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.

Sleepiness (sedation) is a common side effect with INGREZZA. While taking INGREZZA, do not drive a car or operate dangerous machinery until you know how INGREZZA affects you. Drinking alcohol and taking other drugs that may also cause sleepiness while you are taking INGREZZA may increase any sleepiness caused by INGREZZA.

The most common side effect of INGREZZA in people with tardive dyskinesia is sleepiness (somnolence).

The most common side effects of INGREZZA in people with Huntington's disease are sleepiness (somnolence), allergic itching, rash, and trouble getting to sleep or staying asleep.

These are not all of the possible side effects of INGREZZA. 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](tel:1-800-FDA-1088).

Please see INGREZZA full [Prescribing Information](#), including **Boxed Warning**.

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, Parkinson'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](https://www.neurocrine.com), and follow the company on [LinkedIn](https://www.linkedin.com/company/neurocrine), [Twitter](https://twitter.com/neurocrine) and [Facebook](https://www.facebook.com/neurocrine). (*in collaboration with AbbVie)

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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 for the treatment of chorea associated with Huntington's disease (HD), the size of the potential market for INGREZZA for the treatment of chorea associated with HD; the value INGREZZA for the treatment of chorea associated with HD brings to patients; the ability of Neurocrine Biosciences to ensure patients have access to INGREZZA for the treatment of chorea associated with HD; and whether results from INGREZZA for the treatment of chorea associated with HD clinical trials are indicative of real-world results. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements include: risks and uncertainties associated with Neurocrine Biosciences' business and finances in general, as well as risks and uncertainties associated with the commercialization of INGREZZA for the treatment of chorea associated with HD; whether INGREZZA for the treatment of chorea associated with HD receives adequate reimbursement from third-party payors; the degree and pace of market uptake of INGREZZA for the treatment of chorea associated with HD; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA for the treatment of chorea associated with HD; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA for the treatment of chorea associated with HD, and the ability of the Company to manage these third parties; risks that additional regulatory submissions for INGREZZA for the treatment of chorea associated with HD 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 for the treatment of chorea associated with HD; risks that post-approval INGREZZA for the treatment of chorea associated with HD commitments or requirements may be delayed; risks that INGREZZA for the treatment of chorea associated with HD 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 for the treatment of chorea associated with HD; 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 June 30, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

References

1. INGREZZA capsules (package insert). San Diego, CA; Neurocrine Biosciences. 2023.
2. Stimming EF, Claassen DO, Kayson E, et al. Safety and efficacy of valbenazine for the treatment of chorea associated with Huntington disease (KINECT-HD): a phase 3, randomised, double-blind, placebo-controlled trial. *Lancet Neurol.* 2023;22(6): 494-504. doi:10.1016/S1474-4422(23)00127-8

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