# Neurocrine Biosciences Presents New INGREZZA® (valbenazine) Data on Tardive Dyskinesia Improvement and Stability of Psychiatric Symptoms at American Psychiatric Association Annual Meeting 2022

May 23, 2022

SAN DIEGO, May 23, 2022 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that it will present data on the use of INGREZZA® (valbenazine) capsules for the treatment of tardive dyskinesia (TD) at the American Psychiatric Association (APA) Annual Meeting being held in person May 21-25 in New Orleans and virtually June 7-10.

Neurocrine Biosciences, the leading neuroscience-focused company in the treatment of TD, will present findings from a post hoc analysis of two long-term studies of INGREZZA evaluating global TD improvement and stability of psychiatric symptoms (Poster title: Poster #P7-088 Global Improvements and Psychiatric Stability in Adults with Tardive Dyskinesia: Post Hoc Analyses of Two Long-Term Valbenazine Studies). The analysis found that long-term treatment (48 weeks) for TD with once-daily INGREZZA (40 mg or 80 mg) resulted in substantial clinician-rated and self-rated global improvements of TD symptoms while stability of psychiatric symptoms was maintained, regardless of the participant's primary psychiatric condition.

"The findings presented at the APA Annual Meeting provide further insight into aspects of tardive dyskinesia management that are important to patients," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "Treatment of TD symptoms often requires consideration of complex psychiatric conditions. These data demonstrate that stability of psychiatric symptoms is maintained during TD treatment with valbenazine."

**Additional presentations include:**

- Synergy Between VMAT2 Inhibitors and Antipsychotics in Animal Models of Schizophrenia (Poster #P5-080)
- TeleSCOPE: A 2021 Clinician Survey on Telehealth Services to Detect and Treat Tardive Dyskinesia in the Psychiatry and Neurology Outpatient Setting (#Poster P8-079)
- A Novel, Web-Based Patient-Centric Study to Evaluate the Impact of Treatment of Tardive Dyskinesia with Valbenazine: The RxKinect Study (#Poster P8-031)

A full list of all abstracts being presented by Neurocrine Biosciences at the 2022 APA Annual Meeting is available in the poster proceedings on the Annual Meeting Website.

**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 (like antipsychotics) that help control dopamine receptors in the brain. Taking antipsychotics commonly prescribed to treat mental illnesses such as depression, bipolar disorder, schizophrenia and schizoaffective disorder, and certain medications to treat upset stomach, nausea and vomiting 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 INGREZZA® (valbenazine) Capsules**
INGREZZA, a selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is an FDA-approved product indicated for the treatment of adults with tardive dyskinesia, a condition associated with uncontrollable, abnormal, and repetitive movements of the face, torso and/or other body parts.

INGREZZA is thought to work by reducing the amount of dopamine released in a region of the brain that controls movement and motor function, helping to regulate nerve signaling in adults with tardive dyskinesia. VMAT2 is a protein in the brain that packages neurotransmitters, such as dopamine, for transport and release in presynaptic neurons. INGREZZA, developed by Neurocrine

Biosciences, is novel in that it selectively inhibits VMAT2 with no appreciable binding affinity for VMAT1, dopaminergic (including D2), serotonergic, adrenergic, histaminergic, or muscarinic receptors. 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.

**Important Information**

**Approved Use**

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).

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

**Important Safety Information**

**Do not take INGREZZA if you:**

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

**INGREZZA may cause serious side effects, including**:

- **Sleepiness (somnolence).** Do not drive, operate heavy machinery, or do other dangerous activities until you know how INGREZZA affects you.
- **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
    - shortness of breath
    - dizziness or fainting

**Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you faint.**

- **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.

**The most common side effect of INGREZZA is sleepiness (somnolence). Other side effects include** changes in balance (balance problems, dizziness) or an increased risk of falls, headache, feelings of restlessness, dry mouth, constipation, and blurred vision.

These are not all of the possible side effects of INGREZZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
Please see INGREZZA full **Product Information**.

**About Neurocrine Biosciences**
Neurocrine Biosciences is a 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, Parkinson's disease, endometriosis* and uterine fibroids*, as well as over a dozen mid- to late-stage clinical programs in multiple 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, 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 and the value INGREZZA 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 the commercialization of INGREZZA; risks that clinical trial activities may not be predictive of real-world results or of results in subsequent clinical trials;

risks that INGREZZA may be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects or adverse reactions; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; 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 year ended March 31, 2022. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.



View original content to download multimedia:https://www.prnewswire.com/news-releases/neurocrine-biosciences-presents-new-ingrezza-valbenazine-data-on-tardive-dyskinesia-improvement-and-stability-of-psychiatric-symptoms-at-american-psychiatric-association-annual-meeting-2022-301552333.html

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