Neurocrine Biosciences Presents New INGREZZA® (valbenazine) Data at Psych Congress 2021

November 1, 2021

SAN DIEGO, Nov. 1, 2021 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that it presented new data from its movement disorder program for tardive dyskinesia (TD) at the 2021 Psych Congress scientific meeting being held October 29–November 1, 2021.

Key highlights include:

- New pooled analysis from the KINECT clinical trial program and long-term extension studies found that long-term use of INGREZZA® (valbenazine) led to substantial and clinically meaningful improvements in patients ≥ 65 years with tardive dyskinesia, some of the first TD-specific vesicular monoamine transporter 2 (VMAT2) inhibitor data for this age group.
- Presentation of the development of the MIND-TD questionnaire, a novel online questionnaire to help facilitate dialogue between healthcare professionals and patients about the risks, symptoms and impact of TD.
- New real-world data from TeleSCOPE, an observational study, showed that the use of telehealth during the COVID-19 pandemic significantly reduced clinicians' abilities to diagnose, assess, monitor and treat drug-induced movement disorders.
- Characterization of the *in vitro* activity and pharmacokinetic profile of INGREZZA compared to deutetrabenazine confirms a single, specific, potent INGREZZA metabolite with strong VMAT2 affinity and supports once-daily dosing for INGREZZA.

"Presentation of these new data analyses at this year's Psych Congress will continue to help psychiatric healthcare providers further understand the role of INGREZZA in helping people living with tardive dyskinesia," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "These analyses also reflect our continued commitment to provide valuable resources to patients, caregivers and the healthcare community focused on awareness, screening and treatment of tardive dyskinesia."

Presentations include:

INGREZZA – Tardive Dyskinesia

- Effects of Once-Daily Valbenazine in Elderly Adults with Tardive Dyskinesia (Poster # 111)
- A Model-Informed Drug Development Approach Supporting the Approval of a New Valbenazine Dose for Tardive Dyskinesia (Poster # 85)
- Dihydrotetrabenazine (HTBZ) Isomer Pharmacokinetics (PK) After Single Dose Administration of Valbenazine and Deutetrabenazine in Healthy Subjects (Poster # 19)

Movement Disorder Screening and Management

- Development of the MIND-TD Questionnaire as a Screening Tool for Tardive Dyskinesia (Poster # 106)
- TeleSCOPE: A Real-World Study of Telehealth for the Detection and Treatment of Drug-Induced Movement Disorders (Poster # 122)
- Longitudinal Treatment Patterns for Chorea in Patients with Huntington Disease: Data from Enroll-HD (Poster # 41)

The full abstracts being presented by Neurocrine Biosciences at the 2021 Psych Congress can be accessed by registering for the meeting (national.psychcongress.com/rates).

About Tardive Dyskinesia (TD)
Tardive dyskinesia (TD) is an involuntary movement disorder characterized by uncontrollable, abnormal and repetitive movements of the torso, extremities and/or face, which can include hand or foot movements, rocking of the torso, lip smacking, grimacing, tongue protrusion, facial movements or blinking, as well as puckering and pursing of the lips. The condition is associated with taking certain mental health medicines such as antipsychotics, which are commonly prescribed to treat mental illnesses such as bipolar disorder, depression and schizophrenia. 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 accompanying INGREZZA full **Product Information**.

About Neurocrine Biosciences
Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company dedicated to discovering, developing and delivering life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis*, uterine fibroids* and clinical programs in multiple therapeutic areas. For nearly three decades, Neurocrine Biosciences has specialized in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. For more information, visit **neurocrine.com**, and follow the company on **LinkedIn**. *(*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 related to the benefits to be derived from Neurocrine Bioscience's products and product candidates. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: our future financial and operating performance; risks associated with the commercialization of INGREZZA; the impact of the COVID-19 pandemic and efforts to mitigate its spread on our business; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; risks related to the development of our product candidates; risks associated with our dependence on third parties for development and manufacturing activities related to INGREZZA and our product candidates, and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks that our products, and/or our product candidates 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; risks associated with potential generic entrants for our products; risks that clinical development activities may not be completed on time or at all, or may be delayed for regulatory, manufacturing, COVID-19 or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that the potential benefits of the agreements with our collaboration partners may never be realized; and other risks described in our periodic reports filed with the SEC, including without limitation our quarterly report on Form 10-Q for the quarter ended September 30, 2021. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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