Neurocrine Biosciences Presents Data on Improvements Over Time with Long-Term Use of INGREZZA® (valbenazine) Capsules in Older and Elderly Patients at the American Association for Geriatric Psychiatry 2023 Annual Meeting

March 3, 2023

SAN DIEGO, March 3, 2023 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced it will present data analyzing the long-term outcomes of treating tardive dyskinesia (TD) with INGREZZA® (valbenazine) capsules in older (≥55 years) and elderly (≥65 years) patients from two studies (KINECT ™ 3-extension and KINECT ™ 4). These data (Poster #NR-36, Improvements Over Time with Long-Term Valbenazine in Older and Elderly Patients with Tardive Dyskinesia) are being presented at the American Association for Geriatric Psychiatry (AAGP) 2023 Annual Meeting from March 3–6 in New Orleans.

The data demonstrated that long-term treatment with once-daily INGREZZA led to clinically meaningful reductions of TD symptoms in both older patients with TD and elderly patients. At 48 weeks of INGREZZA treatment, >80 percent of participants in the ≥65 years age group met the ≥50 percent improvement in the Abnormal Involuntary Movement Scale (AIMS) response threshold. Analyses included the following:

- Mean change from baseline in AIMS total score
- Percentage of patients meeting AIMS response thresholds, including ≥50 percent improvement from baseline (protocol-defined response) and ≥70 percent improvement from baseline (stringent response)
- Global response thresholds, including Clinical Global Impression of Change-Tardive Dyskinesia (CGI-TD) and Patient Global Impression of Change (PGIC) defined as "much improved" or "very much improved" (score ≤2)

Similar results were found in the ≥55 years age group. Mean changes from baseline to week 48 in psychiatric symptom scale scores were minimal, indicating maintenance of psychiatric stability in both age groups.

"Older and elderly adults treated with dopamine receptor blocking agents, including antipsychotics, have an increased risk for developing TD," said Eiry W. Roberts, MD, Chief Medical Officer at Neurocrine Biosciences. "The results of this post-hoc analysis regarding long-term use of INGREZZA in this vulnerable patient population can be used to better inform treatment decisions for those experiencing TD."

The *Diagnostic Statistical Manual of Mental Disorders (DSM-5-TR)* notes that middle-aged and elderly individuals have an increased risk for TD.

Key findings from the data analyses include:

- In both age groups, mean improvements in AIMS total score increased over time. At week 8 (first pooled post-baseline visit) and week 48 (end of treatment), mean score changes from baseline in the ≥65 years age group were -4.5 and -8.8, respectively
- The percentage of participants in this age group who met response thresholds were as follows: AIMS ≥50 percent improvement (40.0 percent [20/50] and 82.1 percent [23/28] for weeks 8 and 48, respectively); CGI-TD ≤2 (33.3 percent [17/51] and 92.9 percent [26/28]); PGIC ≤2 (43.1 percent [22/51]; and 85.7 percent [24/28]). Similar results were found in participants aged ≥55 years
- Safety analyses indicated similar incidences between age groups for any treatment-emergent adverse event (TEAE) (76.8 percent and 72.7 percent for ≥55 years [n=190] and ≥65 years [n=55], respectively), serious TEAEs (20.5 percent and 18.2 percent); and the most common TEAEs (headache 10.0 percent and somnolence/urinary tract infection 10.9 percent)
- Psychiatric symptom scale scores were minimal, indicating maintenance of psychiatric stability in both age groups

Additional presentation includes:

- Use of Anticholinergics for Drug-Induced Movement Disorders with Implications for Elderly Patients (Poster #NR-35)

The full abstracts being presented by Neurocrine Biosciences at AAGP 2023 are available on the meeting website and can be accessed by registering.

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. 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 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 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.

Please see accompanying 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 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 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 quarter ended December 31, 2022. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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