Neurocrine Biosciences Provides Preliminary Fourth Quarter and Full-Year 2021 Net Product Sales Results and Future Program Milestones

January 6, 2022

INGREZZA® (valbenazine) Preliminary Fourth Quarter Net Product Sales of Approximately $301 Million and 56,400 Total Prescriptions

INGREZZA® (valbenazine) Preliminary Full-Year 2021 Net Product Sales of Approximately $1.1 Billion

Supplemental New Drug Application to the U.S. Food and Drug Administration for Valbenazine for Chorea Associated with Huntington Disease Submission in the Second Half of 2022

Phase 2 Data Readouts for NBI-827104, a Novel T-Type Calcium Channel Blocker, in Essential Tremor and in Epileptic Encephalopathy with Continuous Spike and Wave During Sleep in 2022

SAN DIEGO, Jan. 6, 2022 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today provided an update on its business performance, including preliminary net product sales results of INGREZZA® (valbenazine) for 2021, and key clinical development milestones for 2022 and 2023. Kevin Gorman, Chief Executive Officer of Neurocrine Biosciences, will discuss these updates as part of a webcast presentation at the 40th Annual J.P. Morgan Healthcare Conference to be held virtually on Monday, January 10 at 11:15 a.m. Eastern Time, followed by a Question and Answer session at approximately 11:35 a.m. Eastern Time.

Preliminary Fourth Quarter 2021 INGREZZA® (valbenazine) Net Product Sales (Unaudited) Highlights

- Unaudited preliminary fourth quarter 2021 INGREZZA net sales were approximately $301 million and $296 million on an inventory adjusted basis
- Fourth quarter 2021 INGREZZA net sales and total prescriptions grew 25% and 32% respectively vs. fourth quarter of 2020
- Quarterly growth driven by record patients on therapy exiting 2021
- Commercial expansion to better meet the needs of healthcare professionals across diverse sites of care on track for completion by the end of Q1 2022
- The Company plans to provide full-year 2022 INGREZZA sales guidance on its Q4 and FY 2021 Earnings Call on February 11, 2022

"Our fourth quarter and full-year results highlight INGREZZA's return to growth in a challenging environment. We exited 2021 helping more patients with tardive dyskinesia than ever before. Furthermore, we now have 13 clinical programs in mid-to-late-stage studies which will generate important data readouts over the next two years," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "This year, our priorities are focused on INGREZZA and continuing to advance our broad pipeline. We are uniquely positioned to drive INGREZZA growth and reinvest in our pipeline to develop potential best-in-class medications that are focused on neurological, neuro-endocrine and psychiatric disorders for patients who deserve better treatment options."

Expected Future Milestones and Key Activities

Program	Indication	Milestones / Key Activities
Valbenazine* (VMAT2 Inhibitor)	Chorea in Huntington Disease	File Supplemental New Drug Application in Second Half (2H) 2022
	Adjunctive Treatment of Schizophrenia	Initiate 2nd Registrational Study in 2022; Top-Line Registrational Data in 2023
	Dyskinesia Due to Cerebral Palsy	Top-Line Registrational Data in 2023
NBI-827104** (Selective T-Type Ca_V Channel Blocker)	Essential Tremor	Top-Line Phase 2 Data in Mid-2022
	Rare Pediatric Epilepsy: CSWS	Top-Line Phase 2 Data in 2H 2022
NBI-1117568† (Selective M4 Agonist)	Treatment of Schizophrenia	Initiate Phase 2 Study in 2022
New Chemical Entity	Neurological or Psychiatric Indication	Initiate Phase 1 Study in 2022
Crinecerfont (CRF1 Receptor Antagonist)	Congenital Adrenal Hyperplasia (Adult)	Top-Line Registrational Data in 2023
	Congenital Adrenal Hyperplasia (Pediatric)	Top-Line Registrational Data in 2023

NBI-1065845‡ (AMPA Potentiator)	Inadequate Response to Treatment in Major Depressive Disorder	Phase 2 Data in 2023
NBI-1065846‡ (GPR-139 Agonist)	Anhedonia in Depression	Phase 2 Data in 2023
NBI-921352∞ (Selective $Na_V1.6$ Channel Blocker)	Focal Onset Seizure in Adults	Phase 2 Data in 2023

Key: VMAT2 = Vesicular Monoamine Transporter 2; Ca_V = Calcium Channel, Voltage-Gated; CSWS = Epileptic Encephalopathy with Continuous Spike and Wave During Sleep; M4= M4 Muscarinic Receptor; CFR1 = Corticotropin-Releasing Factor Type 1; AMPA = Alpha-Amino-3-Hydroxy-5-Methyl-4-Isoxazole Propionic Acid; GPR = Orphan G Protein Coupled Receptor; $Na_V1.6$ = Sodium Channel, Voltage-Gated

*Neurocrine Bioscience Partners: * Mitsubishi Tanabe Pharma Corporation has commercialization rights in East Asia;*
*** In-Licensed from Idorsia Pharmaceuticals; † In-Licensed from Sosei Group Corporation; ‡ Partnered with Takeda Pharmaceutical Company Limited; ∞ In-Licensed from Xenon Pharmaceuticals*

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: our preliminary unaudited financial information; the benefits to be derived from our products and product candidates; the value our products and/or our product candidates may bring to patients; the continued success of INGREZZA; our financial and operating performance, including our future revenues, expenses, or profits; our collaborative partnerships; expectations regarding our ability to adapt our business to the evolving COVID-19 pandemic, mitigate its impact on our business, including our ability to continue conducting our ongoing clinical trials and other development activities, to protect the safety and well-being of our employees, to continue to support uninterrupted supply of INGREZZA, and to otherwise advance our business objectives; and the timing of the initiation and/or completion of our clinical, regulatory, and other development activities and those of our collaboration partners. 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 items that may be identified during the financial statement closing process that cause adjustments to the estimates included in this press release; our future financial and operating performance; risks associated with the commercialization of INGREZZA and ONGENTYS; the impact of the evolving COVID-19 pandemic on our business and the business operations of our customers; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; risk and uncertainties related to any COVID-19 quarantine, social distancing and other requirements put in place by governments, customers, or clinical trial sites, including the impact of such requirements on the ability of patients to have in-person visits with their health care provider; risks related to the development of our product candidates; risks associated with our dependence on third parties for development, manufacturing, and commercialization activities for our products and 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 clinical development activities may not be initiated or 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; 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; 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.

This press release refers to preliminary unaudited net sales in certain non-GAAP financial measures. These non-GAAP financial measures should not be considered replacements for, and should be read together with, the comparable GAAP financial measures, which are included in this press release.

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