Neurocrine Biosciences Provides COVID-19 Business Update

April 3, 2020

SAN DIEGO, April 3, 2020 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today provided an update regarding the company's business operations during the COVID-19 pandemic as part of its commitment to prioritize the safety, health and well-being of patients, their caregivers, healthcare providers and employees. The company continues to assess any potential impact to its business given the ongoing nature of the pandemic and plans to provide further updates during its first quarter financial results in early May.

Workplace and Community
We are committed to ensuring the safety and well-being of our employees and their families, as well as the communities in which we serve. In March, the company enacted new internal policies to protect its staff and mitigate the spread of COVID-19.

- To minimize exposure, Neurocrine Biosciences implemented a "Work from Home Policy" for all employees except certain key essential members involved in business-critical activities.
- For business-critical employees, we have implemented safety measures designed to comply with federal, state, and local guidelines.
- Our customer-facing personnel are utilizing remote technologies to ensure continued support for patients and healthcare professionals.
- We have donated supplies to San Diego area hospitals to support our local community's preparedness and response to COVID-19.

We will continue to assess the need to amend or expand existing policies given the fluidity of the situation.

Supporting the Needs of Patients Taking INGREZZA® (valbenazine)
At Neurocrine Biosciences, we are working to ensure that patients with tardive dyskinesia are well supported during this time and have uninterrupted access to INGREZZA.

- Our network of specialty and mental health pharmacies remains engaged with patients to fill prescriptions and support their overall health and well-being during these challenging times.
- We do not expect any disruption in our ability to supply patients with INGREZZA.
- In addition to having ample inventory, we have redundant manufacturing capabilities in place to further mitigate risk of INGREZZA supply disruption.

Crinecerfont Phase II Data in Adults and Global Registrational Study Updates
We look forward to sharing data from the Phase II proof-of-concept study of crinecerfont in adults with classic congenital adrenal hyperplasia (CAH).

- Following the cancellation of the annual meeting of the Endocrine Society in March, we plan to share the full data set from all four patient cohorts at the newly organized ENDO Online 2020 meeting in June.
- In addition, our study abstract, which includes data from the first three patient cohorts only, is expected to be published in the supplement of the *Journal of the Endocrine Society* in Q2.

We continue to perform all activities necessary in preparation to initiate a single, global registrational study of crinecerfont in adult CAH patients in mid-2020.

Opicapone Supply and Launch Timing Update
Neurocrine Biosciences remains committed to serving patients by ensuring that we are well prepared to meet their needs during the ongoing containment efforts related to COVID-19.

- As the COVID-19 pandemic evolves and we continue to seek clarity concerning the ability of our partner, BIAL, to adequately supply commercial inventory of opicapone, we believe it necessary to delay the commercial launch of

opicapone until later this year.
- We will provide incremental updates as we monitor the evolving COVID-19 pandemic and opicapone supply chain situations.
- Our decision to delay the commercial launch is unrelated to the U.S. Food and Drug Administration (FDA) approval process and we look forward to our April 26, 2020 Prescription Drug User Fee Act date.
- We are putting plans in place to launch opicapone later this year and look forward to bringing this important medicine to Parkinson's disease patients in a more stable market environment and ensure continuity of care.

Minimizing Potential Impact on Clinical Studies
We are committed to advancing ongoing clinical studies and working toward key strategic milestones.

- Due to the impact of the COVID-19 pandemic, we are:
  - Temporarily pausing enrollment of new patients in the Phase III study of valbenazine for chorea in Huntington disease, the RESTORE-1 registrational study for NBIb-1817 in Parkinson's disease patients and the Phase IIa pediatric study of crinecerfont in CAH.
  - Diligently working with our clinical site investigators to ensure the safety of all participants already enrolled in our clinical programs.
- We are continuing preparations to ensure that we are well positioned to launch clinical studies planned for the second half of this year which include:
  - Crinecerfont global registrational study in adult CAH patients
  - NBIb-1817 RESTORE-2 registrational study in Parkinson's disease
  - NBI-921352 Phase II study in SCN8A developmental and epileptic encephalopathy, a rare pediatric epilepsy
  - ACT-709478 Phase II study in a rare pediatric epilepsy (pending our decision to exercise an option to license this asset from Idorsia)
- We plan to have on-going studies in three registrational programs and five mid-stage programs by the end of 2020.
- We will provide additional updates should any of our clinical trial timelines change.

About INGREZZA® (valbenazine) Capsules
INGREZZA, a selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is the first 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 from presynaptic neurons. INGREZZA, developed in Neurocrine's laboratories, 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 psychiatric medications such as antipsychotics or antidepressants.

Important Safety Information
Contraindications
INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

Warnings & Precautions

Somnolence
INGREZZA can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by INGREZZA.

QT Prolongation
INGREZZA may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. INGREZZA should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

Parkinsonism
INGREZZA may cause Parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. Reduce the dose or discontinue INGREZZA treatment in patients who develop clinically significant parkinson-like signs or symptoms.

Adverse Reactions
The most common adverse reaction (≥5% and twice the rate of placebo) is somnolence. Other adverse reactions (≥2% and >placebo) include: anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia.

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 INGREZZA full Prescribing Information at www.INGREZZA.com/PI.

About Neurocrine Biosciences
Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with 28 years of experience discovering and developing 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 and endometriosis* and clinical development programs in multiple therapeutic areas including Parkinson's disease, chorea in Huntington disease, congenital adrenal hyperplasia, epilepsy, uterine fibroids* and polycystic ovary syndrome*. Headquartered in San Diego, Neurocrine Biosciences specializes 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 expectations regarding business and financial impacts of the COVID-19 pandemic, including with respect to clinical studies (including timing and patient enrollment), product supply chain, regulatory activities and our other business operations; the benefits to be derived from our products and product candidates, including INGREZZA and opicapone; the value INGREZZA, opicapone, and/or our product candidates may bring to patients; the expected launch of opicapone, including the FDA's regulatory approval process for opicapone; BIAL's ability to adequately resupply opicapone; and the timing of 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 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 quarantines, shelter-in-place and similar government orders that are currently in place or that may be put in place in the future, including the impact of such orders on our business operations and the business operations of the third parties on which we rely; risks associated with the commercialization of INGREZZA; risks that the opicapone NDA may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; 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, opicapone, 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 associated with our dependence on BIAL for development and manufacturing activities related to opicapone, and our ability to manage BIAL; risks that clinical development activities may not be completed on time or at all, or may be delayed for regulatory, manufacturing, 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; and other risks described in our periodic reports filed with the SEC, including without limitation our annual report on Form 10-K for the year ended December 31, 2019. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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