Neurocrine Announces FDA Conditional Acceptance of Proprietary Name INGREZZA™ for VMAT2 Inhibitor Valbenazine

August 31, 2016

SAN DIEGO, Aug. 31, 2016 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced that the U.S. Food and Drug Administration (FDA) has conditionally accepted the proprietary name "INGREZZA™" for the Company's once-daily vesicular monoamine transporter 2 (VMAT2) inhibitor valbenazine. The Company has recently announced the submission of a New Drug Application (NDA) with the FDA for valbenazine in tardive dyskinesia and is also exploring its utility in Tourette syndrome.

The name INGREZZA (pronounced in-GREH-zah) was developed using the FDA's Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names consistent with the goal of preventing medication errors. Additionally, the proprietary name development program included prescribers, pharmacists and linguists to create a unique, memorable name that helps to connote the clinical value of INGREZZA.

The NDA for INGREZZA includes the results from the Kinect 2 and Kinect 3 clinical trials which evaluated over 330 tardive dyskinesia patients. Data from these studies along with the results from another 18 clinical trials, extensive preclinical testing and drug manufacturing data were included in the NDA filing. The Company expects to receive notification of the acceptance of the NDA filing, as well as the timeframe for NDA review from the FDA in October 2016.

About Tardive Dyskinesia

Tardive dyskinesia is characterized by involuntary, repetitive movements of the face: lip smacking, grimacing, tongue protrusion, facial movements or blinking, puckering and pursing of the lips, or the extremities. These symptoms are rarely reversible and there are currently no FDA approved treatments.

About INGREZZA

VMAT2 is a protein concentrated in the human brain that is primarily responsible for re-packaging and transporting monoamines (dopamine, norepinephrine, serotonin, and histamine) in pre-synaptic neurons. INGREZZA (valbenazine), developed in the Neurocrine laboratories, is a novel, highly-selective VMAT2 inhibitor that modulates dopamine release during nerve communication, showing little or no affinity for VMAT1, other receptors, transporters and ion channels. INGREZZA is designed to provide low, sustained, plasma and brain concentrations of active drug to allow for once daily dosing.

Modulation of neuronal dopamine levels in diseases such as tardive dyskinesia, Tourette syndrome, Huntington's chorea, schizophrenia, and tardive dystonia, which are characterized, in part, by a hyperdopaminergic state, should provide symptomatic benefits for patients with these diseases.

Neurocrine has received Breakthrough Therapy Designation from the FDA for INGREZZA in the treatment of tardive dyskinesia.

The Company is also investigating the safety and efficacy of valbenazine in the treatment of Tourette syndrome. The Company has two ongoing placebo-controlled Phase II Tourette syndrome studies evaluating valbenazine in adults and pediatrics, the T-Forward study and T-Force GREEN study, respectively. Each of these studies is expected to enroll up to 90 subjects with Tourette syndrome. Additionally, the Company has recently launched an open-label, fixed-dose rollover study of valbenazine in up to 180 subjects with Tourette syndrome.

About Neurocrine Biosciences

Neurocrine Biosciences, Inc. discovers and develops innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through its novel R&D platform, focused on neurological and endocrine based diseases and disorders. The Company's two lead late-stage clinical programs are elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc., and INGREZZA (valbenazine or NBI-98854), a vesicular monoamine transporter 2 inhibitor for the treatment of movement disorders. Neurocrine intends to maintain certain commercial rights to its VMAT2 inhibitor for evolution into a fully-integrated pharmaceutical company.

Neurocrine Biosciences, Inc. news releases are available through the Company's website via the internet at http://www.neurocrine.com.

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. 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 Neurocrine's business and finances in general, as well as risks and uncertainties associated with INGREZZA development. Specifically, the risks and uncertainties the Company faces include risks that the INGREZZA NDA may not be accepted for filing by the FDA or may not obtain regulatory approval for tardive dyskinesia or such approval may be delayed; risks that additional regulatory submissions may not occur or be submitted in a timely manner; risks that that the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding INGREZZA, including the risk that the FDA may not approve INGREZZA as the proprietary name for valbenazine; risks that INGREZZA development activities for Tourette syndrome may not be completed on time or at all; risks that ongoing INGREZZA development activities may be delayed for regulatory or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that INGREZZA is safe, tolerable or effective, or 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, adverse reactions or incidents of misuse; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA; risks that the Company will be unable to raise additional funding, if required, to complete development of or commercialize INGREZZA; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA; and other risks described in the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2016. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.

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