Neurocrine Biosciences Announces INGREZZA™ (valbenazine) Long-Term Data to be Presented at the 55th Annual Meeting of the American College of Neuropsychopharmacology

December 5, 2016

New One Year Safety and Efficacy Data of INGREZZA in Tardive Dyskinesia Patients

SAN DIEGO, Dec. 5, 2016 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX), a biotechnology company focused on neurological and endocrine related disorders, announced today that two abstracts representing additional data from several clinical trials of the investigational drug INGREZZA™ (valbenazine) are being presented at the Annual Meeting of the American College of Neuropsychopharmacology in Hollywood, Florida. The posters include an evaluation of the safety and effectiveness of long-term dosing of INGREZZA in the treatment of tardive dyskinesia.

The two posters that will be presented at 5:30pm ET on Monday December 5, 2016 are:

- Efficacy of Valbenazine (NBI-98854) in Subjects with Tardive Dyskinesia: Results of a Long-Term Extension Study (KINECT 3 Extension)
- Safety and Tolerability of Valbenazine (NBI-98854) in Subjects with Tardive Dyskinesia: Results of Long-Term Exposure Data from Three Studies

"We are pleased to share the positive and compelling long-term treatment data of INGREZZA in tardive dyskinesia patients with the broader scientific community," said Chris O'Brien, M.D. Chief Medical Officer of Neurocrine Biosciences. "The results presented today are encouraging for both patients and prescribers and demonstrate that INGREZZA has the potential to bring long-term relief to patients suffering from tardive dyskinesia."

The abstracts show that throughout the one year of treatment with INGREZZA, during the blinded, extension phase of the study, subjects continued to demonstrate sustained improvement in the reduction of their tardive dyskinesia symptoms after the six-week placebo-controlled portion of the study was completed. Additionally, the Clinical Global Impression of Tardive Dyskinesia Symptoms showed a clinically meaningful improvement in symptoms at the end of treatment. The one-year safety data indicates that INGREZZA was generally well tolerated, with no notable change in adverse event frequency over the year of dosing. Importantly, the evaluations utilizing various psychiatric scales over the period of treatment showed no worsening of underlying psychiatric health status (schizophrenia or mood disorders).

About Tardive Dyskinesia

Tardive dyskinesia is characterized by involuntary, repetitive movements of the face, trunk, or extremities, including lip smacking, grimacing, tongue protrusion, facial movements or blinking, puckering and pursing of the lips. 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 or NBI-98854), 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, may provide symptomatic benefits for patients with these diseases.

Neurocrine received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) in 2014 for INGREZZA in the treatment of tardive dyskinesia. The New Drug Application (NDA) for INGREZZA for the treatment of tardive dyskinesia is currently under Priority Review with the FDA. The proprietary name INGREZZA has been conditionally accepted by the FDA.

The Company is also investigating the safety and efficacy of INGREZZA in the treatment of Tourette syndrome. The Company has two ongoing placebo-controlled Phase II Tourette syndrome studies evaluating INGREZZA in adults and pediatrics, the T-Forward study and T-Force GREEN study, respectively. Additionally, the Company has recently launched an open-label, fixed-dose rollover study of INGREZZA 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, a vesicular monoamine transporter 2 inhibitor for the treatment of movement disorders. Neurocrine plans to commercialize INGREZZA in the United States upon approval of the NDA by the FDA.

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 may contain 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 (valbenazine) development and

commercialization. Specifically, the risks and uncertainties the Company faces include risks that INGREZZA development activities may not be completed on time or at all; risks that INGREZZA development activities may be delayed for regulatory or other reasons, may fail to demonstrate that INGREZZA is safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that INGREZZA regulatory submissions may not occur or be submitted in a timely manner; risks that INGREZZA may not obtain regulatory approval or that the U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions regarding INGREZZA; 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 or 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 September 30, 2016. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neurocrine-biosciences-announces-ingrezza-valbenazine-long-term-data-to-be-presented-at-the-55th-annual-meeting-of-the-american-college-of-neuropsychopharmacology-300372270.html

SOURCE Neurocrine Biosciences, Inc.

Contact at Neurocrine Biosciences, Investor Relations, (858) 617-7600