Neurocrine Announces Completion of Phase II Clinical Study of VMAT2 Inhibitor INGREZZA™ (valbenazine) in Adults with Tourette Syndrome

January 17, 2017

Eight Week Study Assessed Safety, Tolerability and Efficacy in 124 Adult Subjects
Company to Host Conference Call and Webcast Today at 4:30pm ET/ 1:30pm PT

SAN DIEGO, Jan. 17, 2017 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today the top-line results from the Company's Phase II T-Forward study of INGREZZA ™(valbenazine), a highly-selective small molecule Vesicular Monoamine Transporter 2 (VMAT2) inhibitor, in adults with Tourette syndrome. While the study showed a significant improvement in overall symptoms of Tourette syndrome as evidenced by the Clinical Global Impression of Change (p=0.015), the pre-specified primary endpoint, the change-from-baseline in the Yale Global Tic Severity Scale (YGTSS) at Week 8 was not met (p=0.18). Adverse events were dose dependent and consistent with earlier clinical studies.

"Overall we were very pleased with the conduct of the study, including the investigators' administration of the Yale Global Tic Severity Scale as well as the safety profile of INGREZZA in adults with Tourette syndrome," said Chris O'Brien, Chief Medical Officer of Neurocrine. "Through this initial placebo-controlled study we gained valuable insights into the conduct of clinical trials in Tourette patients, including patient identification methods and appropriate study inclusion/exclusion criteria. As we have done with our previous early Phase II studies in both endometriosis and tardive dyskinesia, we will apply these new insights to future Tourette studies."

"This T-Forward study has provided us with our first experience in applying the Yale Global Tic Severity Scale with adult patients in a placebo-controlled setting. We are pleased with the clinical response observed across the various efficacy assessments," said Kevin Gorman, Chief Executive Officer of Neurocrine. "At present, we are not disclosing specific details of this study in order to avoid the potential introduction of assessment bias in the ongoing Phase II T-Force GREEN study of pediatric Tourette patients. We look forward to the pediatric study readout next quarter and our subsequent discussion with the FDA on our plans for Phase III development of INGREZZA in Tourette syndrome."

T-Forward Study Design

The T-Forward study was a randomized, double-blind, placebo-controlled, multi-dose, parallel group, Phase II study to evaluate the safety, tolerability and efficacy of valbenazine in adults with moderate to severe Tourette syndrome. Two once-daily fixed doses of valbenazine were evaluated vs. placebo in a 1:1:1 randomization. The three-arm study evaluated 124 patients over eight weeks of dosing followed by two weeks off-drug at 32 study centers in the United States. The primary endpoint of this study was a change from baseline of placebo vs. active scores utilizing the YGTSS at the end of Week 8. Tourette symptoms were also evaluated via the Premonitory Urge for Tics Scale as well as the Clinical Global Impression of Change scale, among others.

Conference Call and Webcast at 4:30pm Eastern Time

Neurocrine will host a live conference call and webcast to discuss this press release today at 4:30pm Eastern Standard Time (EST)/ 1:30pm Pacific Standard Time (PST). Participants may access the live conference call by dialing 888-632-3381 (US) or 785-424-1678 (International) and using the conference ID NBIX. The call can also be accessed via the Webcast through Neurocrine's website at http://www.neurocrine.com.

If you are unable to attend the webcast a replay of the conference call will be available approximately one hour after the conclusion of the call by dialing 800-839-1180 (US) or 402-220-0400 (International) using the conference ID NBIX. The call will be archived for one month.

About Tourette syndrome

Tourette syndrome is a neurological disorder that consists of rapid, non-rhythmic stereotyped motor and vocal tics. Motor tics are typically characterized by facial grimacing, head jerks, extremity movements and other dystonic movements. Vocal tics typically include grunting, throat clearing, and repeating words and phrases. The average age at onset for Tourette syndrome is at six years, with symptoms reaching their peak severity at approximately age ten. Tourette syndrome is more commonly diagnosed in males than females and may be associated with attention deficit hyperactivity disorder and obsessive compulsive disorder. There are approximately 400,000 people with Tourette syndrome in the United States.

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. The proprietary name INGREZZA has been conditionally accepted by the U.S. Food and Drug Administration (FDA).

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.

The Company has a pending New Drug Application (NDA) under review by the FDA to utilize INGREZZA for the treatment of tardive dyskinesia. The Company also has another ongoing placebo-controlled Phase II Tourette syndrome study evaluating INGREZZA in pediatrics, the T-Force GREEN study. Additionally, the Company has an ongoing 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 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 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 for both tardive dyskinesia and/or Tourette syndrome. Specifically, the risks and uncertainties the Company faces include risks that the INGREZZA NDA may not obtain regulatory approval from the FDA for tardive dyskinesia or such approval may be delayed or conditioned; risks that additional regulatory submissions, for Tourette syndrome or otherwise, may not occur or be submitted in a timely manner; risks that the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding INGREZZA; 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; risks that ongoing or future INGREZZA clinical trials 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 annual 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.

SOURCE Neurocrine Biosciences, Inc.

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