



Neurocrine Announces INGREZZA™ (valbenazine) New Drug Application for the Treatment of Tardive Dyskinesia has been Accepted for Priority Review by U.S. FDA

October 11, 2016

SAN DIEGO, Oct. 11, 2016 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the New Drug Application (NDA) for INGREZZA™ (valbenazine) for the treatment of tardive dyskinesia. The INGREZZA application has been given a Prescription Drug User Fee Act (PDUFA) target action date of April 11, 2017.

"This is another significant milestone for Neurocrine and more importantly those patients who are suffering from tardive dyskinesia," said Kevin C. Gorman, President and Chief Executive Officer of Neurocrine Biosciences. "We will continue to work with the FDA in their review of the INGREZZA NDA to potentially bring this important treatment option to patients and physicians."

A Priority Review designation accelerates the FDA review timeline from 10 months to 6 months from the date of acceptance of the NDA. The designation directs the FDA's overall attention and resources to the evaluation of applications for drugs that, if approved, would be a significant improvement in the safety or effectiveness of the treatment of a serious condition. INGREZZA (valbenazine) previously received Fast Track status and Breakthrough Designation status from the FDA.

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 submission.

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 FDA in 2014 for INGREZZA in the treatment of tardive dyskinesia. The 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. 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 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 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 obtain regulatory approval from the FDA for tardive dyskinesia or such approval may be delayed or conditioned; risks that additional regulatory submissions 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 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.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/neurocrine-announces-ingrezza-valbenazine-new-drug-application-for-the-treatment-of-tardive-dyskinesia-has-been-accepted-for-priority-review-by-us-fda-300342260.html>

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