Neurocrine Submits New Drug Application for Valbenazine for Treatment of Tardive Dyskinesia

August 29, 2016

SAN DIEGO, Aug. 29, 2016 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for once-daily dosing of valbenazine in treating tardive dyskinesia.

"This is an important milestone in the development of valbenazine for the treatment of tardive dyskinesia, a serious disease for which there is no FDA approved pharmaceutical treatment," said Kevin C. Gorman, President and Chief Executive Officer of Neurocrine Biosciences. "We look forward to working with the FDA in their review of the valbenazine NDA submission to potentially bring this important treatment option to patients and physicians."

The NDA for valbenazine 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. The Company expects to receive notification of the acceptance of the NDA, 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 Valbenazine

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. Valbenazine (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. Valbenazine 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 valbenazine 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 valbenazine, 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 valbenazine development. Specifically, the risks and uncertainties the Company faces include risks that the valbenazine 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 U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions regarding valbenazine; risks that valbenazine development activities for Tourette syndrome may not be completed on time or at all; risks that ongoing valbenazine 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 valbenazine is safe, tolerable or effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that valbenazine 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 valbenazine; risks that the Company will be unable to raise additional funding, if required, to complete development of or commercialize valbenazine; risks and uncertainties relating to competitive products and technological changes that may limit demand for valbenazine; 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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