Neurocrine Announces Initiation of Phase II Clinical Study of VMAT2 Inhibitor Valbenazine in Children and Adolescents with Tourette Syndrome

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Six-Week T-Force GREEN Study to Assess the Safety, Tolerability and Efficacy of Valbenazine in 90 Pediatric Subjects

SAN DIEGO, Feb. 2, 2016 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that it has initiated a Phase II clinical trial for NBI-98854 (valbenazine), a highly selective small molecule Vesicular Monoamine Transporter 2 (VMAT2) inhibitor, in children and adolescents with Tourette syndrome.

The T-Force GREEN study is a randomized, double-blind, placebo-controlled, multi-dose, parallel group, study of up to 90 children and adolescents. Subjects will receive once-daily dosing of valbenazine during a six-week treatment period to assess the safety, tolerability and efficacy of valbenazine in pediatric Tourette patients. The primary endpoint of this study is the change from baseline of the Yale Global Tic Severity Scale between placebo and active treatment groups at the end of week six. Data readout from this study is expected later in 2016.

"Following the favorable results from our two-week T-Force study of valbenazine in pediatric Tourette patients, we are launching the T-Force GREEN study assessing children and adolescents over six weeks of continuous dosing," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine Biosciences. "This study, coupled with the ongoing T-Forward study of adults with Tourette syndrome, will elucidate trial design, efficacy and safety outcomes for discussion with regulatory authorities on the utilization of valbenazine in Tourette syndrome. Additionally, the ongoing Kinect studies of valbenazine in patients with tardive dyskinesia will support our anticipated NDA filing of valbenazine for tardive dyskinesia later this year."

T-Force GREEN Study Design

The T-Force GREEN study is a multicenter, randomized, double-blind, placebo-controlled, multi-dose, parallel group, Phase II study to evaluate the safety, tolerability and efficacy of NBI-98854 in up to 90 pediatric patients with moderate to severe Tourette syndrome. Two once-daily fixed doses of NBI-98854 will be evaluated vs. placebo in a 1:1:1 randomization. The three-arm study will evaluate up to 45 children and 45 adolescents over six weeks of dosing followed by two weeks off-drug at approximately 40 study centers in the United States. The primary endpoint of this study is the change from baseline of the Yale Global Tic Severity Scale between placebo and active treatment groups at the end of week six. Tourette symptoms will also be evaluated via the Rush Video-Based Tic Rating Scale, Premonitory Urge for Tics Scale as well as Clinical Global Impression scales, among others.

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 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, while at the same time having minimal impact on the other monoamines, thereby reducing the likelihood of "off-target" side effects. Valbenazine is designed to provide low, sustained, plasma and brain concentrations of active drug to minimize side effects associated with excessive monoamine depletion.

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 and expects to file a New Drug Application for tardive dyskinesia in 2016.

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 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 NBI-98854 (valbenazine) development. Specifically, the risks and uncertainties the Company faces include risks that NBI-98854 development activities may not be completed on time or at all; risks that NBI-98854 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 NBI-98854 is safe and effective, or may not be predictive of real-world results or of results in subsequent clinical

trials; risks that NBI-98854 regulatory submissions may not occur or be submitted in a timely manner; risks that NBI-98854 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 NBI-98854; risks that NBI-98854 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 NBI-98854; risks that the Company will be unable to raise additional funding, if required, to complete development of NBI-98854; risks and uncertainties relating to competitive products and technological changes that may limit demand for NBI-98854; and other risks described in the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2015. 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-initiation-of-phase-ii-clinical-study-of-vmat2-inhibitor-valbenazine-in-children-and-adolescents-with-tourette-syndrome-300213365.html

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