Neurocrine Announces Initiation of Phase II Clinical Study of VMAT2 Inhibitor NBI-98854 in Adults with Tourette Syndrome

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Eight Week Study to Assess the Safety, Tolerability and Efficacy of Valbenazine in 90 Adult Subjects

SAN DIEGO, Oct. 20, 2015 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that it has expanded the clinical efforts for NBI-98854 (Valbenazine), a highly selective small molecule Vesicular Monoamine Transporter 2 (VMAT2) inhibitor, by initiating a Phase II clinical trial in adults with Tourette syndrome.

The T-Forward study is a randomized, double-blind, placebo-controlled, multi-dose, parallel group, study of up to 90 adults. Subjects will receive once-daily dosing of NBI-98854 during an eight-week treatment period to assess the safety, tolerability and efficacy of NBI-98854 in Tourette patients. The primary endpoint of this study is a change from baseline of placebo vs. active scores utilizing the Yale Global Tic Severity Scale at the end of Week 8. Data readout from this study is expected later in 2016.

"Evaluation of Valbenazine in adults with Tourette syndrome is another important step in fully exploring its potential in movement disorders," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine Biosciences. "We look forward to our T-Force study readout of children and adolescents with Tourette's during this quarter, and our anticipated NDA filing of NBI-98854 for tardive dyskinesia in 2016."

T-Forward Study Design

The T-Forward study is a randomized, double-blind, placebo-controlled, multi-dose, parallel group, Phase II study to evaluate the safety, tolerability and efficacy of NBI-98854 in adults 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 90 patients over eight 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 a change from baseline of placebo vs. active scores utilizing the Yale Global Tic Severity Scale at the end of Week 8. Tourette symptoms will also be evaluated via the Premonitory Urge for Tics Scale as well as Clinical Global Impression of Change 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 NBI-98854

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. 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. NBI-98854 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.

The Company has two distinct Investigational New Drug Applications related to NBI-98854, tardive dyskinesia and Tourette syndrome, open with the Division of Psychiatry Products at the FDA. Neurocrine has received Breakthrough Therapy Designation from the FDA for NBI-98854 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 NBI-98854, 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 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 June 30, 2015. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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