Neurocrine Announces Initiation of a Long-Term Phase II Clinical Study of VMAT2 Inhibitor Valbenazine in Tourette Syndrome

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Six Month Open Label Safety and Tolerability Study of Valbenazine

SAN DIEGO, July 28, 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, adolescents and adults with Tourette syndrome.

This study is an open-label, fixed-dose, study of up to 180 male and female patients with Tourette syndrome, consisting of up to 90 children and adolescents and up to 90 adults. The primary purpose of the study is to assess the long-term safety and tolerability of valbenazine. Enrollment in this long-term study is limited to subjects who have completed either the ongoing placebo-controlled T-Force GREEN or T-Forward studies. Patients will receive once-daily dosing during a twenty-four week treatment period to assess the safety and tolerability of valbenazine.

"We are very pleased with the conduct of our two ongoing placebo-controlled Phase II studies in Tourette syndrome. The clinical sites are successfully reaching out to patients and families for enrollment and the subject characteristics are exactly in line with our expectations," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine Biosciences. "This six-month extension study provides us with necessary longer-term exposure of valbenazine in both children and adults with Tourette syndrome and will assist in designing our planned Phase III program."

Long-Term Phase II Study Design

The study is an open-label, fixed-dose, Phase II study to evaluate the safety and tolerability of NBI-98854 in up to 180 patients with Tourette syndrome. The study will enroll up to 90 pediatric patients and 90 adult patients with moderate to severe Tourette syndrome. Enrollment in this study is restricted to subjects who have completed either the T-Force GREEN or T-Forward Phase II studies. Evaluation of subjects in the study consists of up to three weeks of screening followed by twenty-four weeks of dosing, then followed by four weeks off-drug at approximately 60 study centers in the United States. Once-daily fixed doses of valbenazine will be evaluated for safety and tolerability via standard clinical laboratory tests, monthly physician examinations and safety scale assessments. The dosing regimen for this study is consistent with the two ongoing Phase II studies; T-Force GREEN and T-Forward. During the study, the symptoms of Tourette syndrome will be evaluated utilizing the Yale Global Tic Severity Scale, the Rush Video-Based Tic Rating Scale, Premonitory Urge for Tics Scale as well as Clinical Global Impression scales.

About T-Force GREEN and T-Forward Studies

The T-Force GREEN and T-Forward studies are ongoing multicenter, randomized, double-blind, placebo-controlled, multi-dose, parallel group, Phase II studies to evaluate the safety, tolerability and efficacy of valbenazine. Once-daily fixed doses of NBI-98854 are being evaluated vs. placebo in a 1:1:1 randomization. These studies will each enroll up to 90 patients with moderate to severe Tourette syndrome, the T-Force GREEN is enrolling children and adolescents and the T-Forward is enrolling adults. The primary endpoint of each of these studies is the change from baseline of the Yale Global Tic Severity Scale between placebo and active treatment groups at the end of placebo-controlled treatment. 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 of onset for Tourette syndrome is 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 valbenazine 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 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 regulatory submissions may not occur or be submitted in a timely manner; risks that valbenazine may not obtain regulatory approval for tardive dyskinesia, Tourette syndrome, or at all, or that the U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions regarding valbenazine ; 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 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 March 31, 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-initiation-of-a-long-term-phase-ii-clinical-study-of-vmat2-inhibitor-valbenazine-in-tourette-syndrome-300305753.html

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