Neurocrine Announces Successful Completion of Phase Ib T-Force Study of VMAT2 Inhibitor NBI-98854 in Adolescents and Children with Tourette Syndrome

December 16, 2015

Once-Daily Valbenazine was Safe and Well Tolerated with a 31% Reduction from Baseline in Tourette Symptoms after Two Weeks of Treatment

Phase II Study in Children and Adolescents Planned To Start in First Half of 2016

SAN DIEGO, Dec. 16, 2015 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that it has successfully completed the Phase Ib T-Force study of NBI-98854 (valbenazine), a once-daily, highly selective, small molecule Vesicular Monoamine Transporter 2 (VMAT2) inhibitor. The T-Force Study evaluated several doses of valbenazine in children and adolescents with Tourette syndrome over two weeks of treatment. Valbenazine was generally safe and well tolerated. The Yale Global Tic Severity Scale was also assessed and after two weeks of treatment showed a mean reduction of 31% from baseline scores, with over half of the subjects considered clinical responders. The Company intends to initiate a placebo-controlled Phase II study of valbenazine in children and adolescents with Tourette syndrome during the first half of 2016.

"We are very pleased with the pharmacokinetic profile as well as the safety and tolerability demonstrated by valbenazine in the T-Force study evaluating children and adolescents with Tourette syndrome," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine. "The 31% reduction in Tourette syndrome symptoms as measured by the Yale Global Tic Severity Scale after just two weeks of dosing was corroborated by an improvement in Tourette symptomology as assessed by the treating physician using the Clinical Global Impression in Tourette Syndrome Scale. We will use the PK data to support pediatric dose selection and look forward to initiating a placebo-controlled Phase II study in children and adolescents with Tourette's in 2016."

T-Force Study Design

The T-Force study was an open-label, multiple ascending dose, pharmacokinetic and pharmacodynamic, study that evaluated the safety, tolerability and exposure-response of valbenazine in children and adolescents with Tourette syndrome. A total of 28 subjects were evaluated over 14 days of once-daily dosing followed by seven days off-drug at approximately 10 study centers in the United States. The study was divided into two dosing groups consisting of children (ages 6-11) and adolescents (ages 12-18), and each age group was further divided into three dosing cohorts. Subsequent dose escalations for children and adolescents were based, in part, on the pharmacokinetic and safety data from the previous cohort in each age group. Additionally, the patients' Tourette symptoms were evaluated weekly via the Yale Global Tic Severity Scale, the Premonitory Urge for Tics Scale as well as an overall Clinical Global Impression in Tourette Syndrome Scale.

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 age six, 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.

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 for either tardive dyskinesia or Tourette syndrome, or both,

may not be completed on time or at all; risks that NBI-98854 development activities for either tardive dyskinesia or Tourette syndrome, or both, 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 for either tardive dyskinesia or Tourette syndrome, or both,, 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 for either tardive dyskinesia or Tourette syndrome, or both, 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.

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