Neurocrine Announces Completion of Enrollment into Kinect 3 Tardive Dyskinesia Study

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Pivotal Phase III Study Evaluating NBI-98854

SAN DIEGO, Aug. 13, 2015 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that it has recently completed subject randomization of the Phase III clinical trial (Kinect 3 Study) of its proprietary Vesicular Mono-Amine Transporter 2 (VMAT2) compound NBI-98854 in tardive dyskinesia patients.

The design of the Kinect 3 Study is a randomized, parallel-group, double-blind, placebo-controlled trial of approximately 240 subjects with moderate to severe tardive dyskinesia and an underlying diagnosis of mood disorder, schizophrenia or schizoaffective disorder. The initial six weeks of treatment consists of an efficacy and safety assessment of 80mg and 40mg once-daily NBI-98854 against placebo. This will be followed by an additional 42 weeks of long-term safety assessment where all subjects are randomized in a blinded fashion to either 80mg or 40mg once-daily NBI-98854. Topline efficacy data from the initial six week assessment is expected in the fourth quarter of 2015.

"Completing enrollment of the Kinect 3 study is another milestone in the development of NBI-98854 and we look forward to sharing the top-line results next quarter," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine Biosciences.

Kinect 3 Study Design

The Kinect 3 study is a randomized, parallel-group, double-blind, placebo-controlled, Phase III clinical trial utilizing the capsule formulation of NBI-98854 in moderate to severe tardive dyskinesia patients with underlying schizophrenia, schizoaffective disorder or mood disorder (including bipolar disorder or major depressive disorder). The primary endpoint in the Kinect 3 study is the mean change from baseline in the Abnormal Involuntary Movement Scale (AIMS) as assessed by blinded central raters. The Kinect 3 study will include approximately 240 subjects randomized to either placebo, once daily 40mg of NBI-98854 or once daily 80mg of NBI-98854 for six weeks. Subsequent to the completion of the six week placebo-controlled dosing, all subjects will continue on once daily 40mg or once daily 80mg of NBI-98854 through Week 48.

The Kinect 3 study, along with the previous efficacy studies of NBI-98854, is designed to complete the placebo-controlled clinical efficacy evaluation of NBI-98854 in tardive dyskinesia. In addition to this tardive dyskinesia study, a separate one-year open-label safety study of NBI-98854, Kinect 4, has also been initiated to support the anticipated 2016 filing of a New Drug Application in tardive dyskinesia.

About Tardive Dyskinesia

Tardive dyskinesia is characterized by involuntary, repetitive movements of the extremities: lip smacking, grimacing, tongue protrusion, facial movements or blinking, puckering and pursing of the lips, or involuntary movements of the limbs. These symptoms are rarely reversible and there are currently no approved treatments.

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.

As announced previously, Neurocrine has also received Breakthrough Therapy Designation from the FDA for NBI-98854 in the treatment of tardive dyskinesia.

The Company is also exploring NBI-98854 in an initial Tourette syndrome clinical trial, the T-Force study. This study is an open-label, multi-dose, two-week evaluation of 36 subjects with Tourette syndrome. Children and adolescents enrolled in the trial

are receiving a once-daily dose of NBI-98854 during a two-week treatment period to assess both the safety and tolerability of NBI-98854. Additionally, the Yale Global Tic Severity Scale and the Premonitory Urge for Tics Scale are being utilized during the study to assess the impact of NBI-98854 on the patients' Tourette symptoms. Data read out from the T-Force study is expected in the fourth quarter of 2015.

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-99854 development. Specifically, the risks and uncertainties the Company faces include risks that NBI-99854 clinical development activities may not be completed on time or at all; risks that NBI-99854 clinical 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-99854 is safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that NBI-99854 regulatory submissions may not occur or be submitted in a timely manner; risks that NBI-99854 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-99854; risks that NBI-99854 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-99854; risks that the Company will be unable to raise additional funding, if required, to complete development of NBI-99854; risk and uncertainties relating to competitive products and technological changes that may limit demand for NBI-99854; 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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