Neurocrine Announces Completion Of Enrollment Into Kinect Study For Treatment Of Tardive Dyskinesia

July 1, 2013

Phase IIB Study Evaluating Twelve Weeks of Continuous Dosing With NBI-98854

SAN DIEGO, July 1, 2013 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that it has completed recruitment in the Phase IIb clinical trial (Kinect Study) of its proprietary Vesicular Mono-Amine Transporter 2 compound, NBI-98854. The final subject will randomize this week.

The design of this twelve-week Phase IIb study is a randomized, parallel, double-blind, placebo-controlled trial of 120 subjects with moderate to severe tardive dyskinesia and underlying schizophrenia or schizoaffective disorder. Topline data from the placebo-controlled portion of the trial is expected in approximately ten weeks.

"We are pleased with the baseline characteristics of subjects who have been randomized into this study and the conduct thus far of this clinical trial has been outstanding," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine Biosciences. "Completing enrollment of this Phase IIb study is another milestone in the development of NBI-98854 and we look forward to sharing the top-line results shortly."

Kinect Study Design

The Kinect Study is a randomized, parallel, double-blind, placebo-controlled, Phase IIb clinical trial utilizing the capsule formulation of NBI-98854 in moderate to severe tardive dyskinesia patients with underlying schizophrenia or schizoaffective disorder. This 120 subject study is assessing two doses of once-daily NBI-98854 over a six-week placebo-controlled dosing period. Half of the randomized subjects are receiving placebo and half are receiving one of two doses of NBI-98854. The two NBI-98854 dosing groups consist of a 50mg group for six weeks and a group that will begin at 100mg for the initial two weeks then convert to 50mg for the final four weeks of the placebo-controlled dosing period. Subsequent to the placebo-controlled dosing, all subjects enter a six-week open label safety extension of 50mg of NBI-98854 administered once daily with additional Abnormal Involuntary Movement Scale (AIMS) assessments. The primary endpoint of the study is a comparison of placebo vs. active scores utilizing the AIMS at the end of week six.

About the Abnormal Involuntary Movement Scale (AIMS)

The AIMS is a structured neurological examination that was developed in 1976 and has been used extensively in movement disorder assessments. It consists of ten distinct ratings of regional involuntary body movements that are scored on a zero to four scale with zero being rated as none and four being rated as severe. The primary endpoint of the Kinect Study is the AIMS total dyskinesia score, items one through seven which rate facial, extremity and trunk movement severity.

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 is currently no approved treatment.

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. The Company has completed three-month in vivo toxicology studies to support longer dosing regimens in humans.

NBI-98854 may also be useful in other disorders such as Huntington's chorea, schizophrenia, Tourette's syndrome, and tardive dystonia.

About Neurocrine Biosciences

Neurocrine Biosciences, Inc. is a biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, tardive dyskinesia, uterine fibroids, stress-related disorders, pain, diabetes, insomnia, and other neurological and endocrine-related diseases and disorders. 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 the Company's VMAT2 program and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's VMAT2 program include, but are not limited to; risk that NBI-98854 will not proceed to later stage clinical trials and risk that the Company's clinical trials will fail to demonstrate that NBI-98854 is safe and effective. With respect to its pipeline overall, the Company faces risk that it will be unable to raise additional funding required to complete development of all of its product candidates; risk relating to the Company's dependence on contract manufacturers for clinical drug supply; risks associated with the Company's dependence on corporate partners for development, commercial manufacturing and marketing and sales activities for the Company's partnered programs; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to

competitive products and technological changes that may limit demand for the Company's products; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2012 and on Form 10-Q for the quarter ended March 31, 2013. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.

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