Neurocrine Announces Start Of Phase IIb Study Of VMAT2 Inhibitor NBI-98854 For Treatment Of Tardive Dyskinesia

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Kinect Study to Evaluate Twelve Weeks of Continuous Dosing

SAN DIEGO, Oct. 1, 2012 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that it has initiated a Phase IIb clinical trial (Kinect Study) of its proprietary Vesicular Mono-Amine Transporter 2 compound, NBI-98854. 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 is expected in the second quarter of 2013.

"We are pleased that NBI-98854 is taking the next step in development with this Phase IIb clinical trial," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine Biosciences. "The Kinect Study incorporates key refinements to improve the appropriateness of tardive dyskinesia subjects, reduce the variability in AIMS assessments, and expand our dose response database. This study will provide us with the data necessary to develop the Phase III program for NBI-98854."

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 will assess two doses of once-daily NBI-98854 over a six-week placebo-controlled dosing period. Half of the randomized subjects will receive placebo and half will receive one of two doses of NBI-98854. The two NBI-98854 dosing groups will consist of a 50mg group for six weeks and a group that will begin at 100mg for the initial two weeks then convert to a 50mg for the final four weeks of placebo-controlled dosing period. Subsequent to the placebo-controlled dosing, all subjects will enter a six-week open label safety extension of 50 mg of NBI-98854 administered once daily with additional AIMS assessments. The primary endpoint of the study is a comparison of placebo vs. active scores utilizing the Abnormal Involuntary Movement Scale (AIMS) at the end of week six.

The Company has designated a small panel of independent, blinded AIMS assessors to determine subject eligibility for the Kinect Study. Prior to the randomization of any subject, a video of each potential subject's initial screening AIMS evaluation will be reviewed by a member of this panel to determine whether the individual has moderate to severe tardive dyskinesia. The independent panel is the sole determiner as to whether or not the subject meets the AIMS severity criteria to be eligible for the Kinect Study. Additionally, this central panel will continue to serve as independent quality control monitors of the AIMS assessments during the entire course of the trial.

The Company has also enhanced the training and certification of the site specific, non-treating investigator to administer the AIMS assessments.

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 is assessed on items one through seven which rate facial, extremity and trunk movements, the AIMS total dyskinesia score.

Next Steps for NBI-98854

Another randomized, parallel, placebo-controlled, double-blind, Phase IIb study is planned to assess six-week dosing of NBI-98854 against placebo. This study will assess moderate to severe tardive dyskinesia sufferers with underlying mood disorders, schizophrenia and schizoaffective disorders, and gastrointestinal disorders.

About Tardive Dyskinesia

Tardive dyskinesia is characterized by involuntary, repetitive movements of the extremities: lip smacking, grimacing, tongue protrusion, rapid eye movements or blinking, puckering and pursing of the lips, or impaired movement of the fingers. These symptoms are rarely reversible and there is currently no known 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) among nerve cells. 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 dopamine depletion. The Company has completed three-month in vivo toxicology studies to support longer dosing regimens.

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, stress-related disorders, pain, tardive dyskinesia, uterine fibroids, 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, 2011 and on Form 10-Q for the quarter ended June 30 , 2012. 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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