



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

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### Kinect 2 to Study Patients with Underlying Mood Disorders and Gastrointestinal Disorders

SAN DIEGO, Dec. 18, 2012 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that it has initiated a Phase IIb clinical trial (Kinect 2 Study) of its proprietary Vesicular Mono-Amine Transporter 2 compound, NBI-98854. The design of this six-week Phase IIb study is a randomized, parallel, double-blind, placebo-controlled, dose titration trial of 90 subjects with moderate to severe tardive dyskinesia and underlying mood disorders, gastrointestinal disorders, and schizophrenia or schizoaffective disorder. Topline data is expected in mid-2013.

"The Kinect 2 Study for NBI-98854 will round out our dose response database with over 200 subject exposures to NBI-98854 for up to three months of duration," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine Biosciences. "This extensive dataset will serve as the basis for our end of Phase II meeting with the FDA planned for the second half of 2013."

### Kinect 2 Study Design

The Kinect 2 Study is a randomized, parallel, double-blind, placebo-controlled, dose titration Phase IIb clinical trial utilizing the capsule formulation of NBI-98854 in moderate to severe tardive dyskinesia patients with an underlying mood disorder (e.g., bipolar disorder), schizophrenia or schizoaffective disorder, or a gastrointestinal disorder with exposure to metoclopramide. This 90 subject study will assess once-daily NBI-98854 over a six-week placebo-controlled dosing period. Half of the randomized subjects will receive placebo and half will receive NBI-98854. The NBI-98854 dosing regimen will begin with a once-daily dose of 25mg for the initial two weeks. At the completion of the initial two weeks of dosing, based on certain efficacy and safety criteria, patients may be titrated to a once-daily 50mg dose, or continue on the once-daily 25mg dose for the following two-week period. At the completion of the second two weeks of treatment another efficacy and safety assessment is performed and patients may again be titrated to a once-daily 75mg, 50mg or 25mg dose for the final two weeks of treatment. 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 2 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 2 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

After completion of the ongoing Kinect Study and this Kinect 2 Study, the Company plans to hold an end of Phase II meeting with the FDA to discuss the pivotal Phase III clinical program for NBI-98854.

### 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.

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 September 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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