Neurocrine Biosciences Announces That VMAT 2 Program Begins Enrollment in Second Phase II Clinical Trial

September 19, 2011

INVESTIGATIONAL NEW DRUG APPLICATION ACCEPTED BY FDA

SAN DIEGO, Sept. 19, 2011 /PRNewswire via COMTEX/ --

Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that it has initiated a second Phase II clinical trial of its proprietary Vesicular Mono-Amine Transporter 2 compound, NBI-98854. The design of this second Phase II study is a randomized, double-blind, placebo controlled, cross-over trial, using a within-subject comparison for safety and efficacy evaluation. This 32 patient study will assess once-daily NBI-98854 (12.5mg and 50mg) over a two week dosing period. The primary endpoint of the study will be a comparison of placebo vs. active scores on the Abnormal Involuntary Movement Scale (AIMS).

"This initial placebo controlled trial of NBI-98854 is an important next step for our VMAT2 program," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine Biosciences. "The data derived from this study will guide our dosing selection and treatment regimens for our larger Phase IIb studies that we plan to initiate in the first half of 2012."

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.

Next Steps for NBI-98854

The Company is completing three-month in vivo toxicology studies to support longer dosing regimens. A larger, longer term Phase IIb study is planned to be initiated in early 2012 to assess three-month dosing of NBI-98854.

About the Abnormal Involuntary Movement Scale (AIMS)

The AIMS was developed in 1976, and has been used extensively in movement disorder assessments. It consists of distinct ratings of regional involuntary body movements that are observed during a structured neurological examination. Ratings one through seven score facial, extremity and trunk movements; items eight through ten are overall global judgments of severity, incapacitation and patient awareness. All ten ratings 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 ratings one through seven.

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 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, 2010 and report on Form 10-Q for the quarter ended June 30, 2011. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.