Neurocrine Announces Initiation Of Phase III Study For VMAT2 Inhibitor NBI-98854

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SAN DIEGO, Oct. 20, 2014 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that it has initiated a Phase III clinical trial (Kinect 3 Study) of its proprietary Vesicular Monoamine Transporter 2 compound, NBI-98854. 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 is followed by an additional 46 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 is expected in the second half of 2015.

"The Kinect 3 Study for NBI-98854 is designed to round out our placebo-controlled efficacy dataset for the tardive dyskinesia NDA," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine Biosciences. "This study contributes to the most comprehensive registration effort of a potential therapeutic agent for tardive dyskinesia. We anticipate filing the NDA with the FDA in the second half of 2016."

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 will be 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.

Top-line efficacy data from the initial six weeks of placebo-controlled dosing is expected in the second half of 2015.

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. The Company also intends to conduct a separate one-year, open-label safety study of NBI-98854 to support the anticipated filing of a New Drug Application (NDA) in tardive dyskinesia during 2016.

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.

In addition to this tardive dyskinesia study, the Company has recently initiated a clinical study assessing NBI-98854 in children and adolescents with Tourette syndrome.

The Company has two distinct Investigational New Drug Applications, tardive dyskinesia and Tourette syndrome, open with the Division of Psychiatry Products at the FDA.

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 a wholly owned 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 the Company's VMAT2 program and the 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 the Company's VMAT2 Phase III program in tardive dyskinesia will be delayed for regulatory or other reasons; risk that the guidance provided by the FDA in the End-of-Phase II meeting may be modified or may not lead to regulatory approval; risk that the Company will be unable to complete the Kinect 3 clinical trial in tardive dyskinesia for regulatory or other reasons; risk that the Company will not be able to submit an NDA filing for NBI-98854 tardive dyskinesia as planned; and risk that the Company's Phase III or other clinical trials will fail to demonstrate that NBI-98854 is safe and effective. With respect to its business 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 contractors for clinical drug supply, commercial manufacturing and marketing and sales activities; uncertainties relating to patent protection and intellectual property rights of third parties; 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; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products if approved. The Company also faces the other risks described in the Company's annual report on Form 10-K for the year ended December 31, 2013 and quarterly reports on Form 10-Q for the quarters ended March 31, 2014 and June 30, 2014. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neurocrine-announces-initiation-of-phase-iii-study-for-vmat2-inhibitor-nbi-98854-783581980.html

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