Neurocrine Biosciences Announces Expansion of its Clinical Pipeline

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New Molecular Entity for Essential Tremor Enters Phase I Clinical Investigation

SAN DIEGO, Nov. 4, 2015 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX), a biotechnology company focused on neurological and endocrine related disorders, announced today that the Company's Investigational New Drug (IND) application, filed with the U.S. Food and Drug Administration, for NBI-640756 for patients with essential tremor is now active. NBI-640756 was discovered in the Neurocrine laboratories and the Company has initiated a sequential dose-escalation Phase I safety and pharmacokinetics study exploring NBI-640756 in healthy volunteers, with top-line data expected the first-half of next year.

"Neurocrine's research team has added another facet to our growing franchise in movement disorders by discovering a novel compound that shows great promise in preclinical models of essential tremor," said Kevin C. Gorman, President and Chief Executive Officer of Neurocrine Biosciences. "A successful readout from this initial Phase I study will lead to the initiation of a multiple ascending dose study of NBI-640756 next year."

Phase I Study Design

This Phase I study is a single site, randomized, double-blind, placebo-controlled, sequential dose-escalation, pharmacokinetic study assessing the safety and tolerability of a single dose of NBI-640756 in up to 32 healthy volunteers. The study will be conducted in multiple sequential cohorts of eight subjects per cohort.

About Essential Tremor

Essential tremor is one of the most common neurological disorders in adults, impacting an estimated 10 million Americans (International Essential Tremor Foundation). The disorder is characterized by involuntary, rhythmic, oscillatory movements that most often affect the upper limbs. As the disease progresses, tremor severity often increases and spreads to other parts of the body. Essential tremor has a significant impact on the activities of daily living often resulting in functional disability as the disease progresses and is associated with a high comorbidity rate of social phobia, depression and anxiety. Current pharmacological therapies utilized in the treatment of essential tremor include propranolol and primidone. Deep brain stimulation, an invasive procedure involving the implantation of electrodes within certain areas of the brain, is sometimes utilized for severe essential tremor.

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 NBI-98854, a 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 essential tremor program and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's essential tremor program include, but are not limited to: risk that NBI-640756 will not proceed to later stage clinical trials and risk that the Company's clinical trials will fail to demonstrate that NBI-640756 is safe and/or effective; risks that NBI-640756 may cause unanticipated adverse effects, in the current study or subsequent clinical trials; risks that development activities may not be completed on time or at all; risks that clinical development activities may be delayed or discontinued for regulatory or other reasons, may not be successful or replicate pre-clinical results, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that regulatory submissions may not occur or be submitted in a timely manner; or the risk that NBI-640756 may not obtain regulatory approval. With respect to its pipeline overall, the Company faces risk relating to the Company's dependence on contract manufacturers for clinical drug supply; 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; risks that the U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions regarding the Company's product candidates; and overall risks associated with the process of discovering, developing and commercializing drug candidates that are

safe and effective for use as human therapeutics and the other risks described in the Company's report on Form 10-Q for the quarter ended September 30, 2015. Neurocrine disclaims any 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-biosciences-announces-expansion-of-its-clinical-pipeline-300171789.html

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