April 22, 2013

NEURALSTEM INC.

FDA Approves Neuralstem To Treat Final Cohort In NSI-189 Phase Ib Trial In Major Depressive Disorder

ROCKVILLE, Md., April 22, 2013 /PRNewswire/ -- Neuralstem, Inc. (NYSE MKT: CUR) announced that it has received approval from the Food and Drug Administration (FDA) to begin dosing the third and final cohort of patients in its ongoing Phase Ib to test the safety of NSI-189 in the treatment of major depressive disorder (MDD). NSI-189, the lead compound in Neuralstem's neurogenic small molecule platform, is a proprietary new chemical entity that stimulates new neuron growth in the hippocampus, a region of the brain believed to be implicated in MDD, as well as other diseases and conditions such as: traumatic brain injury (TBI), Alzheimer's disease, and post-traumatic stress disorder (PTSD).

(Logo: https://photos.prnewswire.com/prnh/20061221/DCTH007LOGO)

"We are pleased to progress to the third and final cohort of this trial," said Karl Johe, PhD, Neuralstem Chairman and Chief Scientific Officer. "The efficacy endpoints are all blinded until the conclusion of the trial, but the safety and tolerability of the compound, through the increased dosage in the first two cohorts, remains excellent."

About NSI-189

Neuralstem's patented technology enables the creation of neural stem cell lines from many areas of the CNS, including the hippocampus. The hippocampus is a part of the brain involved in memory and the generation of new neurons. It is also implicated in several major neurological and psychiatric diseases. From its hippocampal neural stem cell lines, Neuralstem has created virtually unlimited amounts of mature neurons and glia in laboratory dishes. These can be used to mimic the natural brain environment in order to test drug effects.

Neuralstem has been engaged in a drug discovery program with these hippocampal stem cell lines since 2000. In 2009, Neuralstem was granted U.S. patents on four first-in-class chemical entities that boost the generation of new neurons. NSI-189, the first of these to be in a clinical trial, significantly stimulates the generation of new hippocampal neurons (neurogenesis) in vitro and in animal models.

NSI-189 is the lead compound in Neuralstem's neurogenic small molecule drug platform, which the company plans to develop into orally administered drugs for MDD and other psychiatric and cognitive disorders as diverse as traumatic brain injury, Alzheimer's disease, and PTSD.

NSI-189 has been shown to stimulate neurogenesis of human hippocampus-derived neural stem cells in-vitro and in vivo. In healthy normal adult mice, NSI-189 stimulated neurogenesis in the hippocampus and significantly increased its volume, apparently by increasing its synaptic network after 28 days of daily oral administration. In mouse models of depression, NSI-189 significantly improved behavioral responses associated with depression. In humans, NSI-189 may reverse the human hippocampal atrophy seen in MDD and other disorders and reverse their symptoms. This program has received significant support from both the *Defense Advanced Research Projects Agency* **(***DARPA) and the National Institutes of Health (NIH).*

About the Trial

The NSI-189/MDD trial is a randomized, double-blind, placebo-controlled, multiple-dose escalating trial evaluating the safety, tolerability, pharmacokinetics and pharmacodynamic effect of NSI-189 in the treatment of MDD. Phase Ia, which was completed in October 2011, tested escalating doses of single administration of NSI-189 in 41 healthy patients. Phase Ib is testing the safety of escalating doses of NSI-189 for 28 daily administrations in 24 depressed patients in three cohorts. This phase of the trial is expected to conclude in the third quarter of 2013.

About Neuralstem

Neuralstem's patented technology enables the ability to produce neural stem cells of the human brain and spinal cord in commercial quantities, and the ability to control the differentiation of these cells constitutively into mature, physiologically relevant human neurons and glia. Neuralstem completed an FDA-approved Phase I safety clinical trial for amyotrophic lateral sclerosis (ALS), often referred to as Lou Gehrig's disease, in February 2013, and has received FDA approval to begin Phase II. Neuralstem has been awarded orphan status designation by the FDA for its ALS cell therapy.

In addition to ALS, the company is also targeting major central nervous system conditions with its NSI-566 cell therapy platform, including spinal cord injury, ischemic stroke and glioblastoma (brain cancer). The company received approval to commence a Phase I safety trial in chronic spinal cord injury in January 2013.

Neuralstem also has the ability to generate stable human neural stem cell lines suitable for the systematic screening of large chemical libraries. Through this proprietary screening technology, Neuralstem has discovered and patented compounds that may stimulate the brain's capacity to generate new neurons, possibly reversing the pathologies of some central nervous system conditions. The company is in a Phase Ib safety trial evaluating NSI-189, its first neurogenic small molecule compound, for the treatment of major depressive disorder (MDD). Additional indications could include traumatic brain injury (TBI), Alzheimer's disease, and post-traumatic stress disorder (PTSD).

For more information, please visit www.neuralstem.com or connect with us on Twitter, Facebook and LinkedIn

Cautionary Statement Regarding Forward Looking Information

This news release may contain forward-looking statements made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements in this press release regarding potential applications of Neuralstem's technologies constitute forward-looking statements that involve risks and uncertainties, including, without limitation, risks inherent in the development and commercialization of potential products, uncertainty of clinical trial results or regulatory approvals or clearances, need for future capital, dependence upon collaborators and maintenance of our intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements. Additional information on potential factors that could affect our results and other risks and uncertainties are detailed from time to time in Neuralstem's periodic reports, including the annual report on Form 10-K for the year ended December 31, 2012.

SOURCE Neuralstem, Inc.