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Neuralstem Presented NSI-189 Preclinical Data in Type 1 and Type 2 Diabetes at the Annual Meeting of the Diabetic Neuropathy Study Group

NSI-189 Shows Prevention and Reversal of Diabetic Neuropathies in Mice

GERMANTOWN, Md., Sept. 12, 2016 (GLOBE NEWSWIRE) -- Neuralstem, Inc. (Nasdaq:CUR), a biopharmaceutical company focused on the development of central nervous system therapies based on its neural stem cell proprietary technology, announced that Karl Johe, Ph.D., Chief Scientific Officer, presented the poster, "Therapeutic Efficacy of NSI-189 in Diabetic Mice," at the Annual Meeting of the Diabetic Neuropathy Study Group of the EASD (European Association for the Study of Diabetes), held in Bucharest, Romania, on September 11th. The data demonstrate the potential for NSI-189 to reverse neuropathies resulting from diabetes in two well-recognized animal models.

Researchers, led by Nigel Calcutt, Ph.D., at University of California San Diego School of Medicine, showed that NSI-189 significantly protected nerve function and structure in mice with induced type 1 diabetes, when given at the beginning of disease, and improved the nerve function and structure, when given eight weeks after disease onset. The mice were evaluated along several well-established indices of neuropathy, including: slowing of motor nerve conductance velocity, painful hypersensitivity of skin, insensitivity to heat, and reduction in dermal and epidermal nerve fiber density. Treatment with NSI-189 significantly improved all of these indices, in comparison to vehicle-treated diabetic animals. Additionally, in a genetic model of type 2 diabetes (*db/db* mouse), NSI-189 treatment showed significant reversal in all of the same indices of neuropathy.

"Diabetes causes irreversible damage to both the central and the peripheral nervous systems," said Nigel Calcutt, Ph.D., lead author and Professor of Pathology at University of California San Diego School of Medicine. "This study demonstrates that NSI-189 may have potential to reduce, and in some cases, reverse the neuropathies caused by diabetes, promoting structural changes that normalize heat and pain sensitivities. If further studies confirm this, we could foresee translation of this therapy into clinical investigation in humans."

NSI-189, Neuralstem's lead neurogenic compound, is in a Phase 2b multi-center trial for the treatment of major depressive disorder (MDD). The company expects to report results in the second half of 2017.

In earlier preclinical studies, the antidepressant and neurogenic effects of NSI-189 were shown to be mediated by a novel mechanism of action and not by either direct inhibition of serotonin or norepinephrine re-uptake or by direct induction of brain-derived neurotrophic factor (BDNF) release, therefore differentiating NSI-189 from currently-available antidepressants. Additionally, receptor-binding studies show that NSI-189 has no appreciable binding activity for known neurotransmitter receptors, transporters, or kinases, suggesting a novel mechanism of action.

“We have been assessing NSI-189’s potential therapeutic utility outside of MDD,” said Karl Johe, PhD, Neuralstem’s Chief Scientific Officer. “Various preclinical studies demonstrate its neurogenic and synaptogenic capacity in the central nervous system. The diabetes study shows NSI-189’s neuroregenerative capacity in the peripheral nervous system. We look forward to further evaluating its neuroregenerative capacity in the central nervous system in future studies such as diabetes-induced central neuropathies which result in cognitive impairment.”

To view the poster, please visit

<http://www.neuralstem.com/pdf/NeuroDiab2016NeuralstemP37final.pdf>.

About Neuralstem

Neuralstem's patented technology enables the commercial-scale production of multiple types of central nervous system stem cells, which are being developed as potential therapies for multiple central nervous system diseases and conditions.

Neuralstem's ability to generate neural stem cell lines from human hippocampus, which were used for systematic chemical screening for neurogenesis effect, has led to the discovery and patenting of molecules that Neuralstem believes may stimulate the brain's capacity to generate new neurons, potentially reversing pathophysiologies associated with certain central nervous system (CNS) conditions.

The company has completed Phase 1a and 1b trials evaluating NSI-189, its first neurogenic small molecule product candidate, for the treatment of major depressive disorder or MDD, and is currently conducting a Phase 2 efficacy study for MDD.

Neuralstem's first stem cell product candidate, NSI-566, a spinal cord-derived neural stem cell line, is under development for treatment of amyotrophic lateral sclerosis (ALS). Neuralstem has completed two clinical studies, in a total of thirty patients, which met primary safety endpoints. In addition to ALS, NSI-566 is also in a Phase 1 study to treat paralysis due to chronic spinal cord injury, as well as in a Phase 1 study to treat paralysis from ischemic stroke.

Cautionary Statement Regarding Forward Looking Information:

This news release contains "forward-looking statements" made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements relate to future, not past, events and may often be identified by words such as "expect," "anticipate," "intend," "plan," "believe," "seek" or "will." Forward-looking statements by their nature address matters that are, to different degrees, uncertain.

Specific risks and uncertainties that could cause our actual results to differ materially from those expressed in our forward-looking statements include 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, 2015, and filed with the Securities and Exchange Commission (SEC) on March 14, 2016, Form 10-Q for the period ended June 30, 2016, and in other reports filed with the SEC.

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