DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive License: Therapeutics and PMA-Approved Diagnostics for Alzheimer's Disease (intranasal delivery), Parkinson's Disease, Neuropathy,Neuropathic Pain, Peripheral Neuropathy, Diabetic Neuropathy, Neurapraxia, Axonotmesis and Neurotmesis

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a start-up exclusive license to AestasRx Inc., which is located in North Carolina, to practice the inventions embodied in the following patents: U.S. Patent 8,597,660, issued December 3, 2013 (HHS reference E–144–2010/0–US–02).

The patent rights in these inventions have been assigned to the United States of America. The prospective start-up exclusive license territory may be worldwide and the field of use may be limited to therapeutics (including small-molecule TFP5 mimetics) and PMA-approved diagnostics for Alzheimer's disease (intranasal delivery only), Parkinson's Disease, neuropathy, neuropathic pain, peripheral neuropathy, diabetic neuropathy, neurapraxia, axonotmesis and neurotmesis.

DATES: Only written comments and/or applications for a license which are received by NINDS Technology Transfer on or before April 25, 2016 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated start-up exclusive license should be directed to: Susan Ano, Ph.D., NINDS Technology Transfer, 31 Center Drive, Suite 8A52, MSC2540, Bethesda, MD 20892; Telephone: (301) 435–5515; Email: *anos@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This invention discloses treating neurodegenerative diseases by administering cyclin dependent kinase 5 (Cdk5) inhibitory peptides derived from P35, the activator of Cdk5. Abnormally hyperactive Cdk5 has been shown to be associated with a variety of neurodegenerative disorders. This invention describes isolated peptide fragments, pharmaceutical compositions and methods for use of such for treating subjects with a neurodegenerative disease, such as Alzheimer's disease (AD), Amyotrophic Lateral Sclerosis (ALS) and Parkinson's disease (PD). An inhibitory fragment, TFP5, disclosed in this invention, has been shown to ameliorate symptoms of AD in disease animal models without any evidence of toxicity. In particular, TFP5 treatment of rat cortical neurons reduced hyperactivation of Cdk5 upon neuronal stress and insults. Following intraperitoneal (ip) injection, TFP5 was capable of crossing the blood-brain barrier and localizing within the brain where it was found to rescue memory deficits and pathology in a double transgenic mouse (APP/PS1) AD model.

The prospective start-up exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated start-up exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 4, 2016.

Susan Ano,

Technology Development Coordinator, NINDS Technology Transfer, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Cooperative Research and Development Agreement (CRADA) Opportunity for Development of an Assay To Detect Genetic Markers Related to Elevated Serum Tryptase in Familial Tryptasemia and Mast Cell Activation Disorders

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), Department of Health and Human Services (HHS) seeks to enter into a CRADA with a commercial partner to collaborate on the development and commercialization of an assay to detect a genetic variation related to mast cell activation disorders.

DATES: Interested CRADA collaborators must submit a confidential proposal summary to the NIAID (attention Amy F. Petrik at the address below) on or before 8 June 2016 for consideration. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest. CRADA proposals submitted thereafter may be considered if a suitable CRADA collaborator has not been selected.

ADDRESSES: Questions should be addressed to Amy F. Petrik, Ph.D., Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, Rockville, MD 20892–9804, Tel: (240) 627–3721 or email: *petrika@niaid.nih.gov.*

SUPPLEMENTARY INFORMATION: Approximately 4–6% of the general Western population exhibit elevated basal levels of serum tryptase. As a mast cell mediator, tryptase is expected to be transiently elevated following allergic stimuli. Sustained elevation of serum tryptase levels can be associated with symptoms of mast cell mediator release (such as flushing, itching and swelling), neuropsychiatric symptoms (such as chronic pain, anxiety and dysautonomia) and gastrointestinal (GI) symptoms (including functional GI disorders like irritable bowel syndrome as well as eosinophilic GI disease) as well as an increased risk for systemic anaphylaxis.

The NIAID Investigators have recently reported that these symptomatic tryptase elevations can be inherited in an autosomal dominant fashion and are associated with the phenotype described above (Lyons, J.J., et al. J Allergy Clin Immunol, 133 (2014), pp. 1471–1474). Through next generation sequencing and linkage analysis the NIAID Investigators identified a structural variant cosegregating with disease. They then developed an assay, based on digital droplet PCR, to identify individuals with this variant, and estimate that 5–8% of Caucasians may have it, and be at risk for being symptomatic.

Under the CRADA, the assay will be developed toward licensure. Due to the relatively high prevalence of serum tryptase elevation, NIAID Investigators