## 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.*

[FR Doc. 2016–08097 Filed 4–7–16; 8:45 am]

**BILLING CODE 4140–01–P**

## 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

anticipate receiving a large number of samples for analysis which would exceed their capacity. A collaborator with the expertise and capacity for implementing a CLIA or FDA approved test for this genetic variant is sought.

A Cooperative Research and Development Agreement (CRADA) is the anticipated collaborative agreement to be entered into with NIAID pursuant to the Federal Technology Transfer Act of 1986, codified as 15 U.S.C. 3710a, and Executive Order 12591 of April 10, 1987, as amended. A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. A CRADA is not a grant, and it is not a contract for the procurement of goods/services. The NIAID is prohibited from transferring funds to a CRADA collaborator. Under a CRADA, NIAID can contribute facilities, staff, materials, and expertise. The CRADA collaborator can contribute facilities, staff, materials, expertise, and funds. The CRADA collaborator will also have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, diagnostics, and treatments that result from the research.

The expected duration of the CRADA with be two (2) to three (3) years.

Dated: April 2, 2016.

**Suzanne Frisbie,**

*Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

[FR Doc. 2016–08100 Filed 4–7–16; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Environmental Health Sciences Special Emphasis Panel; NIH Loan Repayment Program (Clinical and Pediatric Researchers).

*Date:* April 22, 2016.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* NIEHS/National Institutes of Health, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27709 (Virtual Meeting).

*Contact Person:* Rose Anne M. McGee, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–0752, *mcgee1@niehs.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: April 5, 2016.

**Carolyn Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016–08094 Filed 4–7–16; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; 30-Day Comment Request; The Framingham Heart Study (NHLBI)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on 12/31/2015, pages 81830–81832. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Deshiree Belis, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Dr., Suite 6185A, Bethesda, MD 20892, or call non-toll-free number 301–435–1032, or Email your request, including your address to *deshiree.belis@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

*Proposed Collection:* The Framingham Heart Study, 0925–0216, Revision, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

*Need and Use of Information Collection:* This proposal is to extend the Framingham Study to examine the Generation Three Cohort, New Offspring Spouses and Omni Group 2 Cohort, as well as to continue to monitor the morbidity and mortality which occurs in all Framingham Cohorts. The contractor, with the collaborative assistance of NHLBI Intramural staff, will invite study participants, schedule appointments, administer examinations and testing, enter information into computer databases for editing, and prepare scientific reports of the information for publication in appropriate scientific journals. All participants have been examined previously and thus the study deals with a stable, carefully described group. Data are collected in the form of an observational health examination involving such components as blood pressure measurements, venipuncture, electrocardiography and a health interview, including questions about lifestyles and daily living situations. The National Heart, Lung, and Blood Institute uses the results of the Framingham Study to: (1) Characterize risk factors for cardiovascular and lung