

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Title of invention: Vaccines for HIV.

Description of Technology: Although the development of an effective HIV vaccine has been an ongoing area of research, the high variability in HIV-1 virus strains has represented a major challenge in successful development. Ideally, an effective candidate vaccine would provide protection against the majority of clades of HIV. Two major challenges are immunodominance and sequence diversity. One strategy for overcoming these two issues is to identify the conserved regions of the virus and exploit them for use in a targeted therapy.

Researchers at the National Cancer Institute's Vaccine Branch used conserved elements (CEs) of the polypeptides Gag and Env as immunogenic compositions to induce an immune response to HIV-1 envelope polypeptides and Gag polypeptides. conserved elements (CEs) of the polypeptides Gag and Env as immunogenic compositions to induce an immune response to HIV-1 envelope polypeptides and Gag polypeptides. This invention is based, in part, on the discovery that administration of one or more polypeptides comprising CEs, separated by linkers and collinearly arranged, of HIV Env or Gag CE proteins

can provide a robust immune response compared to administration of a full-length Env or Gag protein. The Env-CE DNA vaccines were tested in a rhesus macaque model and were able to induce a cellular and humoral immune response in this model whereas vaccination with the full length DNA did not produce the same effect.

A robust increase in immunity was observed when rhesus macaques were subjected to a prime-boost protocol. First, rhesus macaques were primed with Env-CE DNA and boosted with full length Env resulting in an observed increase in both the cellular and humoral responses. A further increase in immune response was observed from priming with CE and boosting with a combination of CE and full length DNA resulting in a significantly improved breadth of immune responses. These improved protocols may help solve the immunodominance problem observed in current protocols. This is considered a major obstacle for HIV vaccine development. The CE vaccines described by this invention have potential for use as prophylactic and therapeutic HIV vaccines.

Potential Commercial Applications:

- HIV vaccines

Value Proposition:

- Addresses two key hurdles faced by current HIV vaccines: sequence diversity of HIV and immunodominance.

- Induces cross-clade specific immune response.

- The prime-boost immunization regimen is not limited to HIV, but can be employed to improve the induction of immune responses to any subdominant epitopes (cellular or humoral) to increase breadth, magnitude and quality of the immune response.

Development Stage: Pre-clinical (in vivo validation).

Inventor(s): George Pavlakis, Barbara Felber, Antonio Valentin, James Mullins.

Intellectual Property: HHS Reference #E-087-2015/0-US-01, corresponding to U.S. Provisional Patent App. #62/161,123, filed on May 13, 2015, entitled: HIV Env Conserved Element DNA Vaccine.

HHS Reference #E-009-2016/0-US-01, corresponding to U.S. Provisional Patent App. #62/241,599, filed on October 14, 2015, entitled: Prime-Boost combination vaccine to Expand Breadth of Immunological Response.

HHS Reference #E-087-2015/0-PCT-02; corresponding to International Patent App. #PCT/US2016/032317; filed on May 13, 2016, entitled: Methods and Compositions for inducing an immune

response using Conserved Element Constructs.

Publications

- Kulkarni, V. *et al.* *PLoS One*;9:e86254. 2014. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0086254>
- Kulkarni, V. *et al.* *PLoS One* Oct 22;9(10):e111085. doi: 10.1371/journal.pone.0111085. eCollection, 2014. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0111085>

Related Technologies: HHS Reference #E-132-2012/0 Method of Altering the Immunodominance Hierarchy of HIV Gag by DNA Vaccine Expressing Conserved Regions.

Contact Information: Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

Dated: August 2, 2016.

John D. Hewes,

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016-18861 Filed 8-8-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

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 meetings.

The meetings 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Review of Late Arriving K Mechanism Grant Applications.

Date: August 17, 2016.

Time: 8:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892-9529, 301-496-0660, Benzingw@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Clinician Training Program R25 Application Review.

Date: August 17, 2016.

Time: 2:00 p.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite MSC 9529, Bethesda, MD 20892-9529, 301-496-0660, Benzingw@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Biorepository Resource Access Committee (BRAC) X01 Meeting.

Date: August 18, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Joel A. Sayoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223, joel.sayoff@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 3, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-18863 Filed 8-8-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

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SUPPLEMENTARY INFORMATION:

Technology description follows.

Title of invention: Methods of Treating or Preventing Demyelination Using Thrombin Inhibitors and Methods of Detecting Demyelination Using Neurofascin 155.

Description of Technology: Neurofascin 155 is a cell adhesion molecule that attaches myelin to axolemma. Contactin-associated protein (Caspr) is a major component of the perinodes. Perinodal astrocytes regulate nodal structure and myelin thickness by regulating thrombin-dependent cleavage of axo-glia junction attaching the outermost paranodal loops of myelin to the axon membrane. Agents which inhibit the cleavage of Neurofascin 155 or the cleavage of Caspr1 stabilize the node and may impede the immunological attack of myelin where the paranodes are attached to the axon.

The technology is directed to methods of treating diseases characterized by demyelination (such as Multiple sclerosis), white matter injury, or conditions associated with myelin remodeling by administering an agent that inhibits cleavage of Neurofascin 155 or Caspr1. The agent could be a thrombin inhibitor, an agent that inhibits thrombin expression, an anti-thrombin antibody that specifically inhibits thrombin mediated cleavage of Neurofascin 155, a mutated version or fragment of Neurofascin 155 or Caspr1, antibodies to Neurofascin 155 or Caspr1.

The technology also includes methods of detecting remodeling of myelin by detecting changes in levels of Neurofascin 125 and Neurofascin 30 in a biological sample, such as central spinal fluid or blood.

Potential Commercial Applications: Treatment of demyelinating diseases, such as Multiple sclerosis.

Treatment of diseases characterized by white matter injury or myelin remodeling.

Monitoring the amount of or rate of remodeling of myelin to determine the efficacy of agents used demyelinating diseases.

Value Proposition: Agents which inhibit cleavage of Neurofascin 155 or Caspr1 or inhibit thrombin activity are a novel approach to treating demyelinating diseases or diseases characterized by white matter injury.

The methods of detecting modification in the amount or rate of remodeling of myelin can be used to determine the efficacy of treatments of neurological disorders and are less expensive than other methods currently used.

Development Stage: Pre-clinical (in vivo validation).

Inventor(s): R. Douglas Fields <https://science.nichd.nih.gov/confluence/display/snsdp/Home>.

Intellectual Property: HHS Reference No. E-151-2015/0-PCT-02.

PCT application, PCT/US2016/027776, filed April 15, 2016 entitled "Methods of Treating or Preventing Demyelination Using Thrombin Inhibitors and Methods of Detecting Demyelination Using Neurofascin 155".

Publications: 1. In preparation.

Collaboration Opportunity: Researchers at the Eunice Kennedy Shriver National Institute of Child Health and Human Development ("NICHD"), seek CRADA partner or collaboration for development of agents to treat multiple sclerosis or other conditions associated with myelin remodeling by administering an agent that inhibits cleavage of Neurofascin 155 or Caspr1. The agent could be a