BILLING CODE: 4140-01-P

DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health

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.

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:

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-glial 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 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, or antibodies to Neurofascin 155 or Caspr1.

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.

Date: August 2, 2016

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John D. Hewes

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