

Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at the toll-free number 1-855-266-2427 or <http://www.hrsa.gov/cicp/>.

#### XV. Amendments

##### 42 U.S.C. 247d-6d(b)(4)

Amendments to this Declaration will be published in the **Federal Register**.

**Authority:** 42 U.S.C. 247d-6d.

Dated: August 1, 2018.

**Alex M. Azar II**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2018-16856 Filed 8-6-18; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 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 on Aging Initial Review Group; Clinical Aging Review Committee NIA-C.

*Date:* September 27-28, 2018.

*Time:* 3:00 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

*Contact Person:* Alicja L. Markowska, Ph.D., DSC, National Institute on Aging, National Institutes of Health, Gateway Building 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-496-9666, [markowska@nia.nih.gov](mailto:markowska@nia.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 1, 2018.

**Melanie J. Pantoja,**

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

[FR Doc. 2018-16787 Filed 8-6-18; 8:45 am]

**BILLING CODE 4140-01-P**

## 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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S.

**FOR FURTHER INFORMATION CONTACT:** Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479; telephone: 301-402-5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

**SUPPLEMENTARY INFORMATION:** This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve commercialization of results of federally-funded research and development.

Technology description follows.

#### Neuroendocrine Tumor Evans Blue Containing Radiotherapeutics

The invention pertains to a radiotherapeutic against neuroendocrine tumors that express somatostatin receptor. Radionuclide therapies directed against tumors that express somatostatin receptors (SSTRs) have proven effective for the treatment of advanced, low- to intermediate-grade neuroendocrine tumors. The subject radiotherapeutic covered by the subject patent estate includes a somatostatin (SST) peptide derivative like octreotate (TATE), conjugated to an Evans Blue

(EB) analog, and further chelated via DOTA to therapeutic radionuclide<sup>177</sup>Lu, a beta emitter. The EB analog reversibly binds to circulating serum albumin and improves the pharmacokinetics of SST peptide derivatives and reduce peptide-receptor radionuclide therapy toxicity. EB analog conjugated to octreotate (EB-DOTATATE) has been shown by the inventors to provide reversible albumin binding in vivo and extended half-life in circulation. When EB-TATE is slowly released into the tumor microenvironment, tumor uptake and internalization into SSTR positive tumors resulted in delivery of radioactive particles and tumor cell killing. EB-TATE displayed significantly more favorable pharmacokinetics than TATE alone by achieving higher tumor to non-tumor penetration as evidenced by positron emission tomography.

Potential Commercial Applications:

- Cancer therapeutics
  - Higher stability/Lower toxicity
- Development Stage:
- Early stage

*Inventors:* Xiaoyuan Chen and Orit Jacobson Weiss (both of NIBIB).

*Intellectual Property:* HHS Reference No. E-150-2016-1; International Patent Application PCT/US2017/031696.

*Licensing Contact:* Michael Shmilovich, Esq. CLP; 301-435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Dated: July 20, 2018.

**Michael Shmilovich,**

*Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.*

[FR Doc. 2018-16839 Filed 8-6-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive Patent License: Treatment of Type I Diabetes and its Comorbidities

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent License to Inversago Pharma, Inc., located in Montreal, Quebec, Canada, to practice the inventions embodied in the patent applications

listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

**DATES:** Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development August 22, 2018 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone

number 301-435-5019, or *shmilovm@mail.nih.gov*.

**SUPPLEMENTARY INFORMATION:** The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to Inversago Pharma, Inc.:

HHS Reference No.	Patent No. or application No.	Filing date	Title
E-282-2012-0-US-01	61/725,949	November 13, 2012	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-PCT-02	PCT/US2013/069686	November 12, 2013	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-US-03	9,765,031	November 12, 2013	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-CA-04	2889697	April 27, 2015	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-EP-05	13802153.0	June 01, 2015	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-IN-06	3733/DELNP/2015	May 1, 2015	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-JP-07	2015-542015	May 11, 2015	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-CN-08	201380069389.9	July 3, 2015	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-US-09	15/674,365	August 10, 2017	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-US-10	15/674,333	August 10, 2017	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-US-01	61/991,333	May 9, 2014	Cannabinoid Receptor Mediating Compounds.
E-282-2012-1-US-01	62/171,179	June 4, 2015	Cannabinoid Receptor Mediating Compounds.
E-282-2012-1-PCT-02	PCT/US2016/035291	June 1, 2016	Cannabinoid Receptor Mediating Compounds.
E-282-2012-1-EP-05	16728547.7	June 1, 2016	Cannabinoid Receptor Mediating Compounds.
E-282-2012-1-US-08	15/579,123	December 1, 2017	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-PCT-02	PCT/US2015/029946	May 8, 2015	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-AU-03	2015255765	November 7, 2016	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-CA-04	2948349	May 8, 2015	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-EP-06	15728668.3	May 8, 2015	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-CN-05	201580028788.X	May 8, 2015	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-IN-07	201637038171	November 8, 2016	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-JP-08	2017-511558	May 8, 2015	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-US-09	15/309,728	November 8, 2016	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-HK-10	17105705.6	June 9, 2017	Cannabinoid Receptor Mediating Compounds

The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive patent license territory will be granted worldwide and in a field of use not broader than human therapeutics for type I diabetes and its comorbidities diabetic nephropathy, chronic kidney disease, diabetic retinopathy, and peripheral and autonomic neuropathy.

The invention covered by the patents and patent applications pertaining to HHS Ref. No. E-282-2012-0 pertain to cannabinoid receptor 1 (CN<sub>1</sub>R) inverse agonists. CN<sub>1</sub>R activation plays a key role in appetitive behavior and metabolism. Of importance as a therapeutic target here is that the receptor is expressed in both peripheral tissue as well as the central nervous system. The invention is a class of pyrazole compounds that act as CN<sub>1</sub> receptor inverse agonists and have been shown effective at reducing obesity and its associated metabolic consequences while having no experimentally discernable neuropsychotropic side effects that are considered adverse such as the earlier antagonists rimonabant. These CN<sub>1</sub>R receptor compounds were developed with the goals of limiting their brain penetrance without losing

their metabolic efficacy due to CN<sub>1</sub> inverse agonism, and having a primary metabolite directly targeting enzymes involved in inflammatory and fibrotic processes associated with metabolic disorders. The patent rights cover both compositions of matter and methods of use.

The inventions covered by HHS Ref. E-140-2014-0 also pertain to pyrazole CN<sub>1</sub>R receptor inverse agonists. In addition, some of these compounds also have a direct inhibitory effect on inducible nitric oxide synthase (iNOS), whereas another group of the compounds directly activates AMP kinase. There is evidence that the metabolic effects of endocannabinoids are mediated by CN<sub>1</sub> receptors in peripheral tissues. These dual-target compounds may be useful for treating metabolic disease and related conditions such as obesity and diabetes and their complications, including liver or kidney fibrosis, without the dangerous the side effects.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI 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 prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent 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: July 25, 2018.

**Michael A. Shmilovich,**  
Senior Licensing and Patenting Manager,  
National Heart, Lung, and Blood Institute,  
Office of Technology Transfer and  
Development.

[FR Doc. 2018-16836 Filed 8-6-18; 8:45 am]

**BILLING CODE 4140-01-P**