

<https://www.regulations.gov> suitability policy will be posted without change to <https://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>. Written public comments will be provided to ACIP members.

FOR FURTHER INFORMATION CONTACT:

Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MSH24-8, Atlanta, GA 30329-4027; Telephone: 404-639-8367; Email: ACIP@cdc.gov.

SUPPLEMENTARY INFORMATION:

In accordance with 41 CFR 102-3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID-19 pandemic and rapidly evolving COVID-19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID-19 is a Public Health Emergency. A notice of this ACIP meeting has also been posted on CDC's ACIP website at: <http://www.cdc.gov/vaccines/acip/index.html>. In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP.

Purpose: The ACIP is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the ACIP is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the CDC Director and appear on CDC immunization schedules must be covered by applicable health plans.

Matters To Be Considered: The agenda will include discussions on COVID-19 vaccine booster doses. A recommendation vote is scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit <https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: The docket will be opened to receive written comments on January 6, 2022. Written comments must be received on or before January 12, 2022.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the January 5, 2022 ACIP meeting must submit a request at <http://www.cdc.gov/vaccines/acip/meetings/> no later than 11:59 p.m. EST, January 4, 2022, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by 12:00 p.m. EST, January 5, 2022. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3

minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

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Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022-00123 Filed 1-4-22; 4:15 pm]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Human Therapeutics for Fibrotic Disease

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 January 21, 2022 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., CLP Senior Licensing and Patenting Manager, phone number 301-435-5019 or shmilovm@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 license to Inversago Pharma, Inc.:

NIH ref No.	Patent No. or application No.	Issue date	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	September 19, 2017	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	2919779	January 6, 2021	June 01, 2015	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-CH-12	2919779	January 6, 2021	November 12, 2013	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-DE-13	2919779	January 6, 2021	November 12, 2013	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-FR-14	2919779	January 6, 2021	November 12, 2013	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-GB-15	2919779	January 6, 2021	November 12, 2013	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-IE-16	2919779	January 6, 2021	November 12, 2013	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-IN-06	354301	December 23, 2020	May 1, 2015	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-JP-07	6272626	January 12, 2018	May 11, 2015	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-CN-08	ZL201380069389.9	August 20, 2019	July 3, 2015	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-US-09	10,683,270	June 16, 2020	August 10, 2017	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-US-10	10,787,419	September 29, 2020	August 10, 2017	Cannabinoid Receptor Mediating Compounds.
E-282-2012-0-US-11	16/870,093		May 8, 2020	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-US-08	15/579,123		December 1, 2017	Cannabinoid Receptor Mediating Compounds.
E-282-2012-1-US-09	16/438,850		June 12, 2019	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-US-01	61/991,333		May 9, 2014	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-CN-05	201580028788.X	February 7, 2020	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-IN-07	201637038171		November 8, 2016	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-JP-08	6762930	September 11, 2020	May 8, 2015	Cannabinoid Receptor Mediating Compounds.
E-140-2014-0-US-09	10,329,259	June 25, 2019	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 may be worldwide and in a field of use limited to human therapeutics for fibrotic disease.

The invention covered by the patents and patent applications pertaining to NIH Ref. No. E-282-2012-0 and -1 pertain to cannabinoid receptor 1 (CB₁R) inverse agonists. CB₁R 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 CNS. The invention is a class of pyrazole compounds that act as CB₁ receptor inverse agonists and have been shown effective at reducing obesity and its associated metabolic consequences, and for fibrotic disease, while having no experimentally discernable neuropsychotropic side effects that are considered adverse such as the earlier antagonists rimonabant. These CB₁R receptor compounds were developed with the goals of limiting their brain penetrance without losing their metabolic efficacy due to CB₁ inverse agonism, and having a primary metabolite directly targeting enzymes involved in inflammatory and fibrotic processes associated with metabolic disorders. The patents are both compositions of matter and methods of use.

The inventions covered by HHS Ref. E-140-2014-0 also pertain to pyrazole CB₁R 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 CB₁ 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, and includes various fibrotic disorders, 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: January 3, 2022.

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

[FR Doc. 2022-00022 Filed 1-5-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases 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 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Research Topic No. 051 Inhaled Delivery of Clofazimine (CFZ)—An Important Anti-Tuberculosis Drug Phase