

designation annually and assume that an average of 70 hours is needed to prepare such a request.

We estimate 205 respondents will submit 261 requests for fast track designation requests annually and assume that an average of 60 hours is needed to prepare such a request.

Of the requests for fast track designation made per year, we granted approximately 224 requests from 392 respondents, and for each of these granted requests, a premeeting package was submitted. We therefore assume an average burden of 100 hours per respondent for preparing a premeeting package.

Finally, we estimate 33 respondents will submit 38 requests for RMA designation and assume that an average of 60 hours is needed to prepare such a request.

Dated: November 12, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-25414 Filed 11-17-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Public Health Service Act and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting to be held on Tuesday, December 1, 2020. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

DATES: Tuesday, December 1, 2020, 2020, from 10:00 a.m. to 2:45 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required. Please register online at <https://www.cvent.com/d/17qsn> by the deadline of 12:00 p.m. ET on Monday, November 30, 2020. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT:

Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301-443-0721; or ACHDNC@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.*, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

(1) Presentations on the decision making criteria and matrix used to evaluate conditions nominated to the RUSP;

(2) review of newborn screening implementation for the following RUSP conditions: Severe combined immunodeficiency (SCID), critical congenital heart disease (CCHD), Pompe disease, mucopolysaccharidosis type I (MPS I), X-linked adrenoleukodystrophy (XALD); and

(3) overview of the Review of Newborn Screening for Spinal Muscular Atrophy (SMA) report and vote on whether to submit this review to the Secretary.

In July 2018, SMA was added to the RUSP, and the Secretary requested a follow-up report that assesses the

impact of implementing screening for SMA. Following the overview of the Review of Newborn Screening for Spinal Muscular Atrophy report, the Committee is expected to vote on whether to submit this review to the Secretary or whether further action is warranted prior to its submission.

The agenda for this meeting does not include any plans for recommending a condition for inclusion in the RUSP. Agenda items are subject to changes as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, are also available on the ACHDNC website.

Members of the public also will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to provide a written statement or make oral comments to the ACHDNC must be submitted via the registration website by Friday, November 27, 2020, by 10:00 a.m. ET.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

This meeting is being announced less than 15 days prior to the scheduled meeting due to an administrative issue that has now been resolved.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020-25461 Filed 11-17-20; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Treatment and Prevention of Neuropathic Pain With P2Y14 Antagonists

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Saint Louis University, ("SLU"), a non-profit university located in Missouri, in its rights to the inventions and patents listed in the

SUPPLEMENTARY INFORMATION section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NIDDK Technology Advancement Office December 3, 2020 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: Betty B. Tong, Ph.D., Senior Licensing and Patenting Manager, NIDDK Technology Advancement Office, Telephone: 301-451-7836; Email: tongb@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 SLU:

1. U.S. Provisional Patent Application No. 62/877,385, filed July 23, 2019, entitled "Treatment And Prevention Of Neuropathic Pain With P2Y14 Antagonists" (HHS Ref. No. E-144-2019-0-US-01)
2. U.S. Provisional Patent Application No. 63/013,792, filed April 22, 2020, entitled "Treatment And Prevention Of Neuropathic Pain With P2Y14 Antagonists" (HHS Ref. No. E-144-2019-1-US-01)
3. U.S. Patent Application 16/936,951, filed July 23, 2020, entitled "Treatment And Prevention Of Neuropathic Pain With P2Y14 Antagonists" [HHS Ref. No. E-144-2019-2-US-01]

The patent rights in these inventions have been assigned to the Government of the United States of America, and Saint Louis University. The prospective patent license will be for the purpose of consolidating the patent rights to SLU, co-owner of said rights, for commercial development and marketing.

Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200-212. The prospective patent license will be worldwide, exclusive, and may be limited to those fields of use commensurate in scope with the patent rights. It will be sublicensable, and any sublicenses granted by SLU will be subject to the provisions of 37 CFR part 401 and 404.

The invention pertains to methods for treating and preventing neuropathic pain by using selective antagonists for the P2Y14 receptor, a purinergic G protein-coupled receptor that is activated by extracellular UDP-glucose and related nucleotides. The technology provides a method of treating

neuropathic pain by administering a P2Y14 receptor antagonist comprising a naphthalene or phenyl-triazolyl scaffold, potentially increase efficacy of treatments for neuropathic pain, and minimize risk of addiction.

This notice is made pursuant to 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will include terms for the sharing of royalty income with NIDDK from commercial sublicenses of the patent rights and may be granted unless within fifteen (15) days from the date of this published notice the NIDDK 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 that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: November 12, 2020.

Charles D. Niebylski,

Director, Technology Advancement Office, National Institute of Diabetes and Digestive and Kidney Diseases.

[FR Doc. 2020-25455 Filed 11-17-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Population Science and Epidemiology-B.

Date: December 8, 2020.

Time: 10:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gianina Ramona Dumitrescu, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4193-C, Bethesda, MD 28092, dumitrescug@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Electronic Nicotine Delivery Systems—Basic Mechanisms of Health Effects.

Date: December 17-18, 2020.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, (240) 498-7546, diramig@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 13, 2020.

Patricia B. Hansberger,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-25454 Filed 11-17-20; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket Number USCG-2020-0667]

Offshore Patrol Cutter Acquisition Program; Preparation of a Programmatic Environmental Impact Statement/Overseas Environmental Impact Statement

AGENCY: Coast Guard, DHS.

ACTION: Notice of intent to prepare a Programmatic Environmental Impact Statement (PEIS)/Overseas Environmental Impact Statement (POEIS); request for comments.