

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Anti-KK-LC-1 T Cell Receptors for the Treatment of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to StraightLine Bio, Inc. located in Princeton, New Jersey.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before December 26, 2024 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Suna Gulay French, Ph.D., Technology Transfer Manager, NCI Technology Transfer Center at Telephone: (240)-276-5530, Email: suna.gulay@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 62/327,529, filed April 26, 2016 and entitled "Anti-KK-LC-1 T Cell Receptors" [HHS Reference No. E-153-2016-0-US-01];

2. PCT Patent Application No. PCT/US2017/027865, filed April 17, 2017 and entitled "Anti-KK-LC-1 T Cell Receptors" [HHS Reference No. E-153-2016-0-PCT-02];

3. Australian Patent No. 2017258745, issued July 14, 2022 and entitled "Anti-KK-LC-1 T Cell Receptors" [HHS Reference No. E-153-2016-0-AU-03];

4. Canadian Patent Application No. 3021898, filed April 17, 2017 and entitled "Anti-KK-LC-1 T Cell Receptors" [HHS Reference No. E-153-2016-0-CA-04];

5. European Patent No. 3448882, issued November 24, 2021 and entitled "Anti-KK-LC-1 T Cell Receptors" [HHS Reference No. E-153-2016-0-EP-05];

a. Validated in the following jurisdictions: CH, DE, BE, DK, ES, FI, FR, GB, IE, IT, NL, NO and SE.

6. U.S. Patent No. 11,352,410, issued June 7, 2022 and entitled "Anti-KK-LC-1 T Cell Receptors" [HHS Reference No. E-153-2016-0-US-06].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following:

Development, manufacture and commercialization of autologous T cell therapy products that are genetically engineered via retroviral-mediated gene transfer or CRISPR-based gene transfer or transposon-mediated gene transfer to express a T cell receptor (TCR) targeting human Kita-Kyushu Lung Cancer Antigen 1 (KK-LC-1) restricted to HLA-A*01, as claimed in the Licensed Patent Rights, for the treatment of KK-LC-1 positive cancers and premalignant conditions in humans.

For the avoidance of doubt, specifically excluded from the Field of Use are:

1. Development, manufacture, and commercialization of Natural Killer cell therapy products engineered via viral vectors (including lentivirus or retrovirus) to express the TCR(s) claimed in the Licensed Patent Rights; and

2. Development, manufacture and commercialization of a combination therapy for the treatment of KK-LC-1 positive human cancers that do not have the HLA-A*01 genotype, wherein the treatment comprises as a step: Modification of the patient's tumor to express the HLA-A*01 restriction element.

This technology discloses isolated T cell receptors (TCR) reactive to the KK-LC-1 within the context of human leukocyte antigen (HLA) A*01:01. KK-LC-1 is expressed by various epithelial cancers including carcinomas of the bladder, cervix, stomach, breast, lung, and pancreas. Due to its minimal expression in normal tissues, this antigen may be targeted on KK-LC-1—expressing tumors with minimal normal tissue toxicity.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute 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.

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 in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Date: December 6, 2024.

Richard U. Rodriguez,
Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2024-29076 Filed 12-10-24; 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 1009 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 of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Resource Related Research Projects (R24 Clinical Trial Not Allowed).

Date: January 30, 2025.

Time: 10:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G56, Rockville, MD 20892 (Video Assisted).

Contact Person: Maryam Rohani, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G56, Rockville, MD 20892, (301) 761-6656, maryam.rohani@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 4, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-29022 Filed 12-10-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket Number USCG-2021-0183]

Final Programmatic Environmental Impact Statement for the Expansion and Modernization of Base Seattle

AGENCY: Coast Guard, DHS.

ACTION: Notice of Availability; extension of waiting period for the Final Programmatic Environmental Impact Statement Expansion and Modernization of Base Seattle.

SUMMARY: The Coast Guard is extending the waiting period for the Final Programmatic Environmental Impact Statement (PEIS) for the proposed Expansion and Modernization of Base Seattle. We published a Notice of Availability of the Final PEIS on November 15, 2024. That notice marked the start of a 30-day waiting period. We are extending the wait period. January 10, 2025, is the earliest date that the Coast Guard would issue a final decision.

DATES: The Coast Guard will not issue a final decision on the proposed action until at least January 10, 2025.

ADDRESSES: The complete text of the Final PEIS is available in the docket, which can be found by searching the docket number USCG-2021-0183 using the Federal eRulemaking Portal at <https://www.regulations.gov> or at <https://www.dcms.uscg.mil/NEPA>.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be sent to U.S. Coast Guard, Shore Infrastructure Logistics Center, Environmental Management Division, ATTN: Dean Amundson, 1301 Clay Street, Suite 700N, Oakland, CA 94612-5203; phone 510-637-5541; email BaseSeattlePEIS@uscg.mil.

SUPPLEMENTARY INFORMATION: The Final PEIS was prepared in accordance with the requirements of the National Environmental Policy Act (NEPA), the Council on Environmental Quality regulations implementing NEPA (40

CFR 1500-1508), DHS procedures for implementing NEPA (DHS Instruction Manual 023-01-001-01 (series)), Coast Guard Environmental Planning Policy (Commandant Instruction [COMDTINST] 5090.1), and other applicable DHS and Coast Guard policies and guidance. A Notice of Intent (NOI) to prepare the PEIS was published in the **Federal Register** on May 7, 2021 (86 FR 24637). On October 11, 2022, the Coast Guard published a Notice of Availability (NOA) and a request for comments on the Draft PEIS (87 FR 61344). In response to a comment in the Docket the Coast Guard extended the Public Comment Period until December 16, 2022, which was announced in the **Federal Register** (87 FR 73011) and in local newspapers on November 28, 2022.

The NOA for the Final PEIS was published on November 15, 2024, and the original wait period would have concluded on December 16, 2024. The Coast Guard will extend the wait period for the Final PEIS to allow for additional time for public review due to the complexity of the proposed action and the presence of multiple federal holidays during the review period. The Coast Guard will not issue a Record of Decision until after January 10, 2025.

For more detailed information, please see the original notice titled "Final Programmatic Environmental Impact Statement for the Expansion and Modernization of Base Seattle" published on November 15, 2024 (89 FR 90302). A copy of that notice is also available in the docket.

Following the wait period concluding on January 10, 2025, the Coast Guard will announce its Record of Decision, which will be published in the **Federal Register**.

Dated: December 5, 2024.

A. Grable,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Engineering and Logistics.

[FR Doc. 2024-29048 Filed 12-10-24; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA 2024-0034; OMB No. 1660-0068]

Agency Information Collection Activities: Proposed Collection; Comment Request; Federal Hotel and Motel Fire Safety Declaration Form

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of Extension extension and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning a list of hotels, motels, and similar places of public accommodations meeting minimum fire-safety requirements. The information collected is voluntary and if approved for listing, the lodging establishment may be used by Federal employees on government related travel and for Federal agency conferences. As the list is open to use by the public, non-government travelers may use the list to identify lodging meeting minimum life-safety criteria from fire.

DATES: Comments must be submitted on or before February 10, 2025.

ADDRESSES: To avoid duplicate submissions to the docket, please submit comments at www.regulations.gov under Docket ID FEMA-2024-0034. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Teressa Kaas, Fire Program Specialist, FEMA/U.S. Fire Administration, 301-447-1263, and teressa.kaas@