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.*