DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors

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 amending an existing license to include a exclusive patent license to Molecular Targeting Technologies, Inc. (MTTI); a Delaware corporation, with its principle place of business in West Chester, Pennsylvania, to practice the inventions embodied in the patent application 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 July 2, 2019 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 MTTI:

NIH ref No.	Patent No. or patent application No.	Filing date	Title
E–150–2016–0–US–01 ..	62/333,427	May 9, 2019	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E–150–2016–0–PCT–02	PCT/US2017/031696.	May 9, 2017	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E–150–2016–0–CN–03 ..	201780029003X	November 9, 2018 ..	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E–150–2016–0–EP–04 ..	17796666.0	November 12, 2018	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E–150–2016–0–JP–05 ...	2018–558662	November 8, 2018 ..	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E–150–2016–0–US–06 ..	16/099,488	November 7, 2018 ..	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.

The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective patent license will be granted worldwide and limited to the extent that the above referenced patents or patent applications cover lutetium-177 radiotherapeutics for somatostatin-receptor expressing neuroendocrine tumors.

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. 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.

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: June 3, 2019.

Michael A. Shmilovich,

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

[FR Doc. 2019–12708 Filed 6–14–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, 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 Tailored Therapeutics, LLC. (''Tailored''), located in Potomac, MD.

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 July 2, 2019 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: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530, MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702; Telephone: (240)-276–5484; Facsimile: (240)-276–5504; Email: *andy.burke@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

Group A

HLA–A3-Restricted T Cell Receptors Against Mutated RAS

1. U.S. Provisional Patent Application 62/749,750, filed October 24, 2018 (E–166–2018–0–US–01).

HLA Class II-Restricted T Cell Receptors Against RAS With G12R Mutation

1. U.S. Provisional Patent Application 62/795,203, filed January 22, 2019 (E–029–2019–0–US–01).

Group B

Methods of Producing T Cell Populations Using Hydroxycitric Acid and/or a Salt Thereof

1. U.S. Provisional Patent Application 62/661,941, filed April 24, 2018 (E–094–2018–0–US–01); and
2. International Patent Application PCT/US2019/028513, filed April 22, 2019 (E–094–2018–0–PCT–02).

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 fields of use may be limited to the following:

Fields of Use Applying to Intellectual Property Groups A and B

''Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered by CRISPR to express T cell receptors reactive to mutated KRAS, as claimed in the Licensed Patent Rights, for the treatment of human cancers. Specifically excluded from this field of use are retrovirally-engineered peripheral blood T cell therapy products for the treatment of human cancers.

Development, manufacture and commercialization of companion diagnostics approved or cleared by the FDA or equivalent foreign regulatory agency for Licensee-proprietary T cell therapy products.''

Fields of Use Applying to Intellectual Property Group B

''Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered by CRISPR to express T cell receptors reactive to mutated p53, as claimed in the Licensed Patent Rights, for the treatment of cancer in humans.

''Development, manufacture and commercialization of autologous, tumor infiltrating lymphocyte (TIL)-based adoptive T cell therapy products reactive to mutated p53, isolated as claimed in the Licensed Patent Rights, for the treatment of human cancers. Specifically excluded from this field of use are genetically engineered TIL cell therapy products for the treatment of human cancers.

Development, manufacture and commercialization of companion diagnostics approved or cleared by the FDA or equivalent foreign regulatory agency for Licensee-proprietary T cell therapy products.''

Intellectual Property Group A is primarily directed to isolated T cell receptors (TCRs) reactive to mutated Kirsten rat sarcoma viral oncogene homolog (KRAS), within the context of several human leukocyte antigens (HLAs). Mutated KRAS, which plays a well-defined driver role in oncogenesis, is expressed by a variety of human cancers, including: pancreatic, lung, endometrial, ovarian and prostate. Due to its restricted expression in precancerous and cancerous cells, this antigen may be targeted on mutant KRAS-expressing tumors with minimal normal tissue toxicity.

Intellectual Property Group B is primarily directed to methods of preparing isolated populations of T cells by culturing them in the presence of hydroxycitric acid and/or a salt thereof, and methods of treating cancer using populations of T cells cultured in such a manner.

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 which 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 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: June 3, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019–12707 Filed 6–14–19; 8:45 am]

BILLING CODE 4140–01–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 Special Emphasis Panel; High Priority Research Networks.

Date: June 26, 2019.

Time: 12:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Ave, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Kimberly Firth, Ph.D., National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7702, *firthkm@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing