Addiction Research Programs, National Institutes of Health, HHS)

Dated: February 1, 2019.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–01412 Filed 2–6–19; 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 Ziopharm Oncology, Inc. (''Ziopharm''), headquartered in Boston, MA.

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 February 22, 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

E–028–2015: Anti-Mutated KRAS T Cell Receptors

1. US Provisional Patent Application 62/084,654, filed November 26, 2014 (E–028–2015–0–US–01);

2. International Patent Application PCT/US2015/062269, filed November 24, 2015 (E–028–2015–1–PCT–01);

3. Australian Patent Application 2015353720, filed May 18, 2017 (E–028–2015–1–AU–02);

4. Canadian Patent Application 2968399, filed May 18, 2017 (E–028–2015–1–CA–03);

5. Chinese Patent Application 201580070673.7, filed June 23, 2017 (E–028–2015–1–CN–04);

6. European Patent Application 15807756.0 filed June 23, 2017 (E–028–2015–1–EP–05);

7. Israeli Patent Application 252258, filed May 14, 2017 (E–028–2015–1–IL–06);

8. Japanese Patent Application 527874/2017, filed May 24, 2017 (E–028–2015–1–JP–07);

9. Korean Patent Application 2017–7017289, filed June 23, 2017 (E–028–2015–1–KR–08);

10. Mexican Patent Application MX/a/2017/006865, filed May 25, 2017 (E–028–2015–1–MX–09);

11. New Zealand Patent Application 732045, filed May 18, 2017 (E–028–2015–1–NZ–10);

12. Saudi Arabian Patent Application 517381608, filed May 25, 2017 (E–028–2015–1–SA–11);

13. Singapore Patent Application 11201704155U, filed May 23, 2017 (E–028–2015–1–SG–12);

14. United States Utility Patent Application 15/528,813, filed May 23, 2017 (E–028–2015–1–US–13); and

15. Hong Kong Patent Application 18103250.9, filed March 7, 2018 (E–028–2015–1–HK–14).

E–180–2015: Anti-Mutated KRAS T Cell Receptors

1. US Provisional Patent Application 62/171,321, filed June 5, 2015 (E–180–2015–0–US–01).

E–265–2015: T Cell Receptors Recognizing HLA–CW8 Restricted Mutated KRAS

1. US Provisional Patent Application 62/218,688, filed September 15, 2015 (E–265–2015–0–US–01);

2. International Patent Application PCT/US2016/050875, filed September 9, 2016 (E–265–2015–0–PCT–02);

3. Australian Patent Application 2016323017, filed March 6, 2018 (E–265–2015–0–AU–03);

4. Canadian Patent Application 2998869, filed March 15, 2018 (E–265–2015–0–CA–04);

5. Chinese Patent Application 201680058891.3, filed April 3, 2018 (E–265–2015–0–CN–05);

6. European Patent Application 16770408.9 filed March 7, 2018 (E–265–2015–0–EP–06);

7. Israeli Patent Application 257840, filed March 4, 2018 (E–265–2018–0–IL–07);

8. Japanese Patent Application 513423/2018, filed March 13, 2018 (E–265–2015–0–JP–08);

9. Korean Patent Application 2018–7010326, filed April 12, 2018 (E–265–2015–0–KR–09);

10. Mexican Patent Application MX/a/2018/003062, filed March 12, 2018 (E–265–2015–0–MX–10);

11. New Zealand Patent Application 740714, filed March 14, 2018 (E–265–2015–0–NZ–11);

12. Saudi Arabian Patent Application 518391109, filed March 13, 2018 (E–265–2015–0–SA–12);

13. Singapore Patent Application 11201802069U, filed March 13, 2018 (E–265–2015–0–SG–13); and

14. United States Utility Patent Application 15/758,954, filed March 9, 2018 (E–265–2015–0–US–14).

E–175–2016: Anti-KRAS G12D T Cell Receptors

1. US Provisional Patent Application 62/369,883, filed August 2, 2016 (E–175–2016–0–US–01); and

2. International Patent Application PCT/US2017/044615, filed July 31, 2017 (E–175–2016–0–PCT–02).

E–181–2017: HLA Class II-Restricted T Cell Receptors Against Mutated RAS

1. US Provisional Patent Application 62/560,930, filed September 20, 2017 (E–181–2017–0–US–01);

2. International Patent Application PCT/US2018/051641, filed September 19, 2018 (E–181–2017–0–PCT–02);

3. Argentine Patent Application P180102695, filed September 20, 2018 (E–181–2017–0–AR–03);

4. Taiwan Patent Application 107133221, filed September 20, 2018 (E–181–2017–0–TW–05); and

5. United States Utility Patent Application 16/135,231, filed September 19, 2018 (E–181–2017–0–US–06).

E–239–2017: HLA Class I-Restricted T Cell Receptors Against Mutated RAS

1. US Provisional Patent Application 62/594,244, filed December 4, 2017 (E–239–2017–0–US–01); and

2. International Patent Application PCT/US2018/063581, filed December 3, 2018 (E–239–2017–0–PCT–02).

E–166–2018: HLA–A3-Restricted T Cell Receptors Against Mutated RAS

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

Group B

E–237–2017–0: T Cell Receptors Recognizing Mutated P53

1. US Provisional Patent Application 62/565,383, filed September 29, 2017 (E–237–2017–0–US–01); and
2. International Patent Application PCT/US2018/051285, filed September 17, 2018 (E–237–2017–2–PCT–01).

Group C

E–098–2018: T Cell Receptors Which Recognize Mutated EGFR

1. US Provisional Patent Application 62/665,234, filed May 01, 2018 (E–098–2018–0–US–01).

Group D

E–237–2017–1: Methods of Isolating T Cells Having Antigenic Specificity for a P53 Cancer-Specific Mutation

1. US Provisional Patent Application 62/565,464, filed September 29, 2017 (E–237–2017–1–US–01); and
2. International Patent Application PCT/US2018/051280, filed September 17, 2018 (E–237–2017–1–PCT–02).

Group E

E–182–2017: Methods for Selectively Expanding Cells Expressing a TCR with a Murine Constant Region

1. US Provisional Patent Application 62/568,339, filed October 5, 2017 (E–182–2017–0–US–01); and
2. International Patent Application PCT/US2018/052432, filed September 24, 2018 (E–182–2017–0–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 Group A

''Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered by transposon-mediated gene transfer 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, a) retrovirally-engineered peripheral blood T cell therapy products for the treatment of human cancers, and b) CRISPR-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 transposon-mediated gene transfer to express T cell receptors reactive to mutated P53, as claimed in the Licensed Patent Rights, for the treatment of human cancers. Specifically excluded from this field of use are CRISPR-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 C

''Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered by transposon-mediated gene transfer to express T cell receptors reactive to mutated EGFR, as claimed in the Licensed Patent Rights, 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 D

''Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered by transposon-mediated gene transfer to express T cell receptors 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 CRISPR-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 E

''Development, manufacture and commercialization of autologous, peripheral blood T-cell therapy products engineered by non-viral gene transfer to express tumor-reactive T cell receptors, as claimed in the Licensed Patent Rights, 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 isolated TCRs reactive to mutated tumor protein 53 (TP53 or P53), within the context of several HLAs. *P53* is the archetypal tumor suppressor gene and the most frequently mutated gene in cancer. Contemporary estimates suggest that >50% of all tumors carry mutations in *P53.* Because of its prevalence in cancer and its restricted expression to precancerous and cancerous cells, this antigen may be targeted on mutant P53-expressing tumors with minimal normal tissue toxicity.

Intellectual Property Group C is primarily directed to isolated TCRs reactive to mutated epidermal growth factor receptor (EGFR), within the context of HLA DPA1*02:01 and HLA DPB1*01:01. EGFR is a transmembrane protein involved in cell growth and proliferation signaling. Mutations in the gene encoding EGFR can lead to its overexpression, causing several types of cancer (*e.g.,* non-small cell lung cancer (NSCLC)). Because of its prevalence in certain cancers and its restricted expression to precancerous and cancerous tissues, this antigen may be targeted on mutant EGFR-expressing tumors with minimal normal tissue toxicity.

Intellectual Property Group D is primarily directed to methods of isolating T cells which are reactive to mutated P53 antigens. Briefly, pools of 25-mer peptides covering known P53 ''hotspot'' mutations have been generated. These peptides may be pulsed into autologous antigen presenting cells which are subsequently co-cultured with the patient's isolated T

cells. Reactive T cells are then purified and may be used as source material for the further isolation of mutant P53-targeting TCRs.

Intellectual Property Group E is primarily directed to a method of selectively sorting and expanding T cells which have been engineered to stably express a murine-human hybrid TCR; a TCR wherein the human constant region has been replaced with the corresponding murine constant region sequences. Unlike typical OKT3 antibody-mediated cell expansion protocols, which operate in a non-specific manner to stimulate all T cells via the CD3 complex, the H57 antibody utilized in the claimed method(s) binds specifically to the mouse constant region domain of the hybrid TCR, leading to selective expansion of T cells expressing the desired exogenous receptor.

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 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: January 30, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019–01431 Filed 2–6–19; 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 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Psychosocial Risks and Disease Prevention.

Date: February 21, 2019.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Weijia Ni, Ph.D., Chief/Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3100, MSC 7808, Bethesda, MD 20892, 301–594–3292, *niw@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: February 2, 2019.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–01444 Filed 2–6–19; 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 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Mechanisms of Emotion, Stress and Health.

Date: February 21, 2019.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, 301–500–5829, *sechu@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: February 2, 2019.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–01459 Filed 2–6–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Traceback Testing: Increasing Identification and Genetic Counseling of Mutation Carriers through Family-based Outreach (U01).

Date: March 6, 2019.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W242 Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Zhiqiang Zou, MD, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities,