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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 Athenex, Inc. ("Athenex") headquartered in Buffalo, NY.

**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 September 28, 2021 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, Telephone: (240)-276-5530; Email: [suna.gulay@nih.gov](mailto:suna.gulay@nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Intellectual Property

##### GROUP A:

*E-237-2017-0/2: T Cell Receptors Recognizing Mutated P53*

1. US Provisional Patent Application 62/565,383, filed September 29, 2017 (E-237-2017-0-US-01);

2. International Patent Application PCT/US2018/051285, filed September 17, 2018 (E-237-2017-2-PCT-01);

3. Australian Patent Application 2018342246, filed September 17, 2018 (E-237-2017-2-AU-02);

4. Brazilian Patent Application BR112020006012-7, filed September 17, 2018 (E-237-2017-2-BR-03);

5. Canadian Patent Application 3977024, filed September 17, 2018 (E-237-2017-2-CA-04);

6. Chinese Patent Application 201880074539.8, filed September 17, 2018 (E-237-2017-2-CN-05);

7. Costa Rica Patent Application 2020-0170, filed September 17, 2018 (E-237-2017-2-CR-06);

8. Eurasian Patent Application 202090757, filed September 17, 2018 (E-237-2017-2-EA-07);

9. European Patent Application 18780006.5, filed September 17, 2018 (E-237-2017-2-EP-08);

10. Israeli Patent Application 273515, filed September 17, 2018 (E-237-2017-2-IL-09);

11. India Patent Application 202047013911, filed September 17, 2018 (E-237-2017-2-IN-10);

12. Japanese Patent Application 2020-517556, filed September 17, 2018 (E-237-2017-2-JP-11);

13. Korean Patent Application 2020-7012344, filed September 17, 2018 (E-237-2017-2-KR-12);

14. Mexico Patent Application MX/a/2020/003504, filed September 17, 2018 (E-237-2017-2-MX-13);

15. New Zealand Patent Application 763023, filed September 17, 2018 (E-237-2017-2-NZ-14);

16. Singapore Patent Application 11202002636P, filed September 17, 2018 (E-237-2017-2-SG-15);

17. United States Utility Patent Application 16/651,242, filed September 17, 2018 (E-237-2017-2-US-16); and

18. Hong Kong Patent Application 62020021272.3, filed November 30, 2020 (E-237-2017-2-HK-17).

*E-135-2019: T Cell Receptors Recognizing R175H or Y220C Mutation in P53*

1. US Provisional Patent Application 62/867,619, filed June 27, 2019 (E-135-2019-0-US-01);

2. International Patent Application PCT/US2020/039785, filed June 26, 2020 (E-135-2019-0-PCT-02); and

3. Taiwanese Patent Application 109121744, filed June 26, 2020 (E-135-2019-0-TW-03).

*E-173-2020: T Cell Receptors Recognizing R273C or Y220C Mutation in P53*

1. US Provisional Patent Application 63/074,747, filed September 4, 2020 (E-173-2020-0-US-01).

*E-098-2018: T Cell Receptors Which Recognize Mutated EGFR*

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

2. International Patent Application PCT/US2019/030108, filed May 1, 2019 (E-098-2018-0-PCT-02);

3. Australian Patent Application 2019263233, filed May 1, 2019 (E-098-2018-0-AU-03);

4. Canadian Patent Application 3,099,106, filed May 1, 2019 (E-098-2018-0-CA-04);

5. European Patent Application 19723615.1, filed May 1, 2019 (E-098-2018-0-EP-05); and

6. United States Utility Patent Application 17/051,860, filed May 1, 2019 (E-098-2018-0-US-06).

*E-165-2020: HLA Class II-Restricted DRB T Cell Receptors Against RAS With G12D Mutation*

1. US Provisional Application 63/050,9131, filed July 13, 2020 (E-165-2020-0-US-01); and

2. International Patent Application PCT/US2021/041375, filed July 13, 2021 (E-165-2020-0-PCT-02).

*E-172-2020: HLA Class II-Restricted DRB T Cell Receptors Against RAS With G12V Mutation*

1. US Provisional Application 63/052,502, filed July 16, 2020 (E-172-2020-0-US-01); and

2. International Patent Application PCT/US2021/041737, filed July 15, 2021 (E-172-2020-0-PCT-02).

*E-189-2020: HLA Class II-Restricted DQ T Cell Receptors Against RAS With G13D Mutation*

1. US Provisional Application 63/086,674, filed October 2, 2020 (E-189-2020-0-US-01).

*E-190-2020: HLA Class I-Restricted T Cell Receptors Against RAS With G12V Mutation*

1. US Provisional Application 63/060,340, filed August 3, 2020 (E-190-2020-0-US-01) and U.S., PCT and foreign patent applications claiming priority to the aforementioned application.

##### GROUP B:

*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);

2. International Patent Application PCT/US2018/051280, filed September 17, 2018 (E-237-2017-1-PCT-02);

3. Australian Patent Application 2018342245, filed September 17, 2018 (E-237-2017-1-AU-03);

4. Canadian Patent Application 3080274, filed September 17, 2018 (E-237-2017-1-CA-04);

5. Chinese Patent Application 201880063656.4, filed September 17, 2018 (E-237-2017-1-CN-05);

6. European Patent Application 18782605.2, filed September 17, 2018 (E-237-2017-1-EP-06);

7. Israeli Patent Application 273516, filed September 17, 2018 (E-237-2017-1-IL-07);

8. Japanese Patent Application 2020-517553, filed September 17, 2018 (E-237-2017-1-JP-08);

9. Korean Patent Application 2020-7012343, filed September 17, 2018 (E-237-2017-1-KR-09);

10. Singapore Patent Application 11202002635R, filed September 17, 2018 (E-237-2017-1-SG-10);

11. United States Utility Patent Application 16/650,696, filed September 17, 2018 (E-237-2017-1-US-11); and

12. Hong Kong Patent Application 62020021274.9, filed November 30, 2020 (E-237-2017-1-HK-12).

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 allogeneic Natural Killer T (NKT) cell therapy products engineered via viral and non-viral means, including CRISPR modification, to express T cell receptors reactive to mutated P53, KRAS, and EGFR within the context of multiple HLAs, as claimed in the Licensed Patent Rights, for the treatment of human cancers. For the purposes of this license, NKT cells are a subset of peripheral blood lymphocytes specifically and intentionally isolated based on unique characteristics of NKT cells resulting in a manufactured clinical product containing at least 50% NKT cells.”

Fields of Use Applying to Intellectual Property Group B

“Development, manufacture, and commercialization of allogeneic Natural Killer T (NKT) cell therapy products engineered via viral and non-viral means, including CRISPR modification, to express T cell receptors reactive to mutated P53, isolated as claimed in the Licensed Patent Rights, for the treatment of human cancers. For the purposes of this license, NKT cells are a subset of peripheral blood lymphocytes specifically and intentionally isolated based on unique characteristics of NKT cells resulting in a manufactured clinical product containing at least 50% NKT cells.”

Intellectual Property Group A description is as follows:

E-237-2017-0, E-135-2019 and E-173-2020 patent rights are 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.

E-165-2020, E-172-2020, E-189-2020 and E-190-2020 patent rights are primarily directed to isolated 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.

E-098-2018 patent rights are primarily directed to isolated TCRs reactive to mutated epidermal growth factor receptor (EGFR), within the context of HLA DPA1\*02:01 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 B description is as follows:

E-237-2017-1 patent rights are primarily directed to methods of rapidly isolating T cells which are reactive to mutated P53 antigens. Briefly, pools of 25-mer peptides covering all known P53 “hotspot” mutations have been generated. These peptides may be pulsed into antigen presenting cells which are subsequently co-cultured with 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.

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.

Dated: September 7, 2021.

**Richard U. Rodriguez,**

*Associate Director, Technology Transfer Center, National Cancer Institute.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[L14400000 PN0000 HQ350000 212; OMB Control Number 1004-0012]

### Agency Information Collection Activities; Application for Land for Recreation or Public Purposes

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Land Management (BLM) proposes to renew an information collection.

**DATES:** Interested persons are invited to submit comments on or before October 13, 2021.

**ADDRESSES:** Written comments and recommendations for this information collection request (ICR) should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR, contact Susie Greenhalgh by email at [lgreenhalgh@blm.gov](mailto:lgreenhalgh@blm.gov), or by telephone at 202-302-4288. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1-800-877-8339 for TTY assistance. You may also view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

**SUPPLEMENTARY INFORMATION:** In accordance with the PRA and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new,