

entitled “Devices for Tissue Cryopreservation and Recovery” and; United States Patent App. No. pending (NIH Ref. E-094-2016-0-US-03); Australia Patent App. No. 2018214954 filed 01/31/18 (NIH Ref. E-094-2016-0-AU-04); Canada Patent App. No. pending (NIH Ref. E-094-2016-0-CA-05); EPC Patent App. No. pending (NIH Ref. E-094-2016-0-EP-06); Japan Patent App. No. pending (NIH Ref. E-094-2016-0-JP-07); each “A Self-contained Cryopreservation and Recovery Device for Tissue Storage, Shipping and Recovery”;

- United States Provisional Patent App. No. 62/644,175, filed 03/16/18 (NIH Ref. E-058-2018-0-US-01) entitled “Using Machine Learning And/ or Neural Networks to Validate Stem Cells and Their Derivatives for Use in Cell Therapy, Drug Discovery and Diagnostics”; PCT Patent App. No. pending (NIH Ref. E-058-2018-0-PCT-02) entitled “Using Machine Learning And/or Neural Networks to Validate Stem Cells and Their Derivatives (2-D Cells And 3-D Tissues) for Use in Cell Therapy And Tissue Engineered Products”;

- United States Patent App. No 62/769,484, filed 11/19/18 (NIH Ref. E-015-2019-0-US-01) entitled “Biodegradable Tissue Replacement Implant and its Use”;

and all U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned 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:

“The development, production and commercialization of allogeneic cell grafts of manufactured Retinal Pigment Epithelium cell(s) alone, or in combination with photoreceptor cells, and on a biodegradable support scaffold transplanted subretinally for intra-ocular ophthalmic treatment of conditions of degeneration, dysfunction or terminal injury of retinal pigment epithelium and/or photoreceptors in humans.”

The technologies relate to development of compositions, devices and processes for production and delivery of RPE-containing tissue graft therapies for treating a range of retinal function disorders, including retinal degenerative conditions in humans.

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 completed 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 26, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019-21520 Filed 10-2-19; 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 October 18, 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-029-2019: 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

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

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

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.”

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.

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: September 26, 2019.

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

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BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Chemical and Petrochemical Inspections (Groves, TX), as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Chemical and Petrochemical Inspections (Groves, TX), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Chemical and Petrochemical Inspections (Groves, TX), has been approved to gauge petroleum and certain petroleum products and

accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of September 25, 2018.

DATES: Chemical and Petrochemical Inspections (Groves, TX) was approved and accredited, as a commercial gauger and laboratory as of September 25, 2018. The next triennial inspection date will be scheduled for September 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Shey, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202-344-1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Chemical and Petrochemical Inspection, 5300 39th Street, Groves, TX 77619 has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Chemical and Petrochemical Inspections (Groves, TX) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
12	Calculations.
17	Marine Measurement.

Chemical and Petrochemical Inspections (Groves, TX) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27-05	D 4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27-08	D 86	Standard Test Method for Distillation of Petroleum Products.
27-48	D 4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or

gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to

CBPGaugersLabs@cbp.dhs.gov. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. <http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories>.