

Dated: July 3, 2019.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2019-14821 Filed 7-11-19; 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: Autologous Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20

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 Kite Pharma, Inc. (“Kite”) located in Santa Monica, CA.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before July 29, 2019 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: David A. Lambertson, 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) 276-5530; Facsimile: (240) 276-5504 Email: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 62/732,263, filed 17 September 2018 and entitled “Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20 and Their Uses” [HHS Reference No. E-205-2018-0-US-01]; and U.S. and foreign patent applications claiming priority to the aforementioned application.

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:

“The development, production and commercialization of an anti-CD19 anti-CD20 dual targeting chimeric antigen receptor (CAR)-based immunotherapy using autologous (meaning one individual is both the donor and the recipient) immune cells transfected with either a viral or non-viral vector, wherein the vector expresses a CAR having at least:

- (1) A dual antigen specificity;
- (2) the complementary determining region (CDR) sequences of the anti-CD19 antibody known as Hu19;
- (3) the complementary determining region (CDR) sequences of the anti-CD20 antibody known as 2.1.2; and
- (4) a T cell signaling domain;

for the treatment of B-cell derived human cancers.”

This technology discloses the development of chimeric antigen receptors that recognize both the CD19 and CD20 cell surface proteins. CD19 and CD20 are expressed on the cell surface of several hematological malignancies, including Non-Hodgkins Lymphoma (NHL), acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL). Although the FDA has recently approved CAR-based therapies which target only CD19 (Yescarta, Kymriah), tumors are capable of undergoing tumor antigen escape (the downregulation of target antigen expression on tumor cells), which results in gradual resistance to “single target therapies.” As a result, patients receiving single target CAR therapies are susceptible to relapse. This has prompted investigators to pursue dual targeting CAR therapies to provide as a means of overcoming tumor antigen escape, thereby providing a more comprehensive therapeutic alternative. The development of a new therapeutic targeting both CD19 and CD20 will benefit public health by offering up an improved treatment for patients that would otherwise be subject to relapse due to tumor antigen escape.

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: July 2, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019-14823 Filed 7-11-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

All of Us Research Program, Tribal Consultation Meetings and Listening Sessions; Correction

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; correction.

SUMMARY: The Department of Health and Human Services, National Institutes of Health published a Notice in the **Federal Register** on June 3, 2019. That Notice requires a correction in the **DATES** and **SUPPLEMENTARY INFORMATION** sections.

FOR FURTHER INFORMATION CONTACT: The *All of Us* Tribal Engagement team by phone at 240-515-5317, by email at AOUTribal@nih.gov, or by mail at 6011 Executive Boulevard, Suite 214, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION: On June 3, 2019, the Department of Health and Human Services, National Institutes of Health published a Notice in the **Federal Register** on pages 25551-25552 (84 FR 25551) that provided two dates for the HHS Regional Consultation, Regions 1-4 (Washington, DC) session to take place on July 16, 2019 and August 21, 2019. The purpose of this Notice is to correct the date within the Dates and Supplemental Information sections for the Regional Washington DC consultation session to read: July 17, 2019. A full schedule of consultations and listening sessions will be made available on the *All of Us* Tribal Engagement web page at <https://AllofUs.nih.gov/All-Us-Tribal-Engagement>.

Dated: July 8, 2019.

Daniel R. Hernandez,

Federal Register Officer, National Institutes of Health.

[FR Doc. 2019-14861 Filed 7-11-19; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2019-0420]

Certificate of Alternative Compliance for the Cable Ferry TINA FALLON

AGENCY: Coast Guard, DHS.

ACTION: Notification of issuance of a certificate of alternative compliance.

SUMMARY: The Coast Guard announces that the Fifth District, Chief of Prevention Division has issued a certificate of alternative compliance from the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), for the cable ferry, TINA FALLON, Official Number (O.N.) 1206170, Chesapeake Shipbuilding Corporation Hull Number 89. We are issuing this notice because its publication is required by statute. Due to its construction, purpose and operation, the cable ferry, TINA FALLON cannot fully comply with the light, shape, or sound signal provisions of the 72 COLREGS without interfering with the vessel's design, operation and construction. This notification of issuance of a certificate of alternative compliance promotes the Coast Guard's marine safety mission.

DATES: The Certificate of Alternative Compliance was issued on July 2, 2019.

FOR FURTHER INFORMATION CONTACT: For information or questions about this notice call or email LCDR Ronaydee M. Marquez, District Five, Asst. Chief, Inspections and Investigations, U.S. Coast Guard; telephone: 757-398-6682, email: Ronaydee.M.Marquez@uscg.mil.

SUPPLEMENTARY INFORMATION: The United States is signatory to the International Maritime Organization's International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as amended. The special construction or purpose of some vessels makes them unable to comply with the light, shape, or sound signal provisions of the 72 COLREGS. Under statutory law, however, specified 72 COLREGS provisions are not applicable to a vessel of special construction or purpose if the Coast Guard determines that the vessel cannot comply fully with those

requirements without interfering with the special function of the vessel.¹

The owner, builder, operator, or agent of a special construction or purpose vessel may apply to the Coast Guard District Office in which the vessel is being built or operated for a determination that compliance with alternative requirements is justified,² and the Chief of the Prevention Division would then issue the applicant a certificate of alternative compliance (COAC) if he or she determines that the vessel cannot comply fully with 72 COLREGS light, shape, and sound signal provisions without interference with the vessel's special function.³ If the Coast Guard issues a COAC, it must publish notice of this action in the **Federal Register**.⁴ Because TINA FALLON operates within Coast Guard Fifth District, this office is authorized to issue the COAC.

The Fifth District, Chief of Prevention Division, U.S. Coast Guard, certifies that the TINA FALLON, O.N. 1206170 is a vessel of special construction or purpose, and that, with respect to the requirement for sidelights and sternlights it is not possible to comply fully with the requirements enumerated in the 72 COLREGS, without interfering with the normal operations or design of the vessel. Installing navigation or running lights along the centerline would interfere with the open deck as the vessel has a pilot house superstructure set to one side of the vessel for loading and parking vehicles. Additionally, the installation of sidelights and sternlights on this vessel will be inconsequential as the vessel operates on a direct cable crossing on the Nanticoke River, Connecting Road 577 in Delaware on an unscheduled 600-foot route. While the vessel is underway, the cable is raised, and yellow flashing warning lights on the primary slip automatically actuate whenever the cable is raised, thereby warning up and down river traffic when the vessel is crossing. Due to the design and nature of the operation, it is impossible for any vessel traffic to cross the route due to the cable, therefore, the requirement for sidelights or sternlights have been omitted. Installation of these lights is inconsequential and would not pose a safety risk as no vessel traffic can cross or overtake. Additionally, due to the short nature of the trip, the requirement for sidelights and sternlights would interfere with the vessel's operations, and create a burden

¹ 33 U.S.C. 1605.

² 33 CFR 81.5.

³ 33 CFR 81.9.

⁴ 33 U.S.C. 1605(c) and 33 CFR 81.18.

on the operator to continuously switch the navigation lights on and off after each 5 minute transit.

The vessel will install the mast lights and restricted in ability to maneuver lights (RAM) on the superstructure mast at proper height. The Fifth District, Chief of Prevention Division further finds and certifies that the mast light and RAM lights are in the closes possible compliance with the applicable provisions of the 72 COLREGS.⁵

This notice is issued under authority of 33 U.S.C. 1605(c) and 33 CFR 81.18.

Dated: July 9, 2019.

J.A. Stockwell,

Acting Chief, CDR, U.S. Coast Guard, Prevention Division, Fifth Coast Guard District.

[FR Doc. 2019-14848 Filed 7-11-19; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2019-0264]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625-0105.

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625-0105, Regulated Navigation Area; Reporting Requirements for Barges Loaded with Certain Dangerous Cargoes, Inland Rivers, Eighth Coast Guard District and the Illinois Waterway, Ninth Coast Guard District; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before August 12, 2019.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2019-0264] to the Coast

⁵ 33 U.S.C. 1605(a); 33 CFR 81.9.