

licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Pitts, Ph.D., 240-669-5299; [elizabeth.pitts@nih.gov](mailto:elizabeth.pitts@nih.gov). Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

**SUPPLEMENTARY INFORMATION:** Technology description follows.

### Protein Nanoparticle-Based Vaccine for Influenza Virus

#### Description of Technology

There is a great need for a broadly protective, “universal” influenza virus vaccine. Most influenza vaccines target the head of the influenza surface glycoprotein hemagglutinin (HA). However, this region of the HA protein undergoes fast antigenic drift. The current strategy to address this issue is to reformulate influenza vaccines annually against dominant circulating strains, but this leads to variable protective efficacy against annual epidemic strains and will not provide protection against novel influenza viruses with pandemic potential. A “universal” influenza vaccine could improve seasonal vaccination and provide pandemic preparedness.

Broadly neutralizing antibodies with heterosubtypic binding have been discovered. However, commercial development of vaccines that produce broadly neutralizing antibodies has so far been unsuccessful. Researchers at NIAID used structure-guided techniques to identify and develop nanoparticles that express a conserved peptide from the HA stem, a preferred antigen for influenza vaccine development as it evolves slower than the HA head. The nanoparticles of this invention elicit antibodies to the HA stem, confer protection in mouse challenge models, are cross-reactive to heterosubtypic HA subtypes, and are heat stable. Additionally, the protein platform of the nanoparticles can be expressed for group 1 and group 2 influenza HA (H1 to H16), which allows mixing of

antigens. This vaccine technology has great potential to provide protection against both annual influenza outbreaks and pandemic-potential influenza viruses.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

#### Potential Commercial Applications

- Vaccines against influenza virus.
- Universal influenza virus vaccine.

#### Competitive Advantages

- Broad/universal protection against both seasonal and pandemic-potential influenza viruses.
- Nanoparticles allow mixing of antigens.
- Incorporates epitopes from group 1 and groups 2 influenza viruses.
- Stability of particle and immunogenicity after high temperature exposure.

#### Development Stage

- In vivo data assessment (animal).

*Inventors:* Audray K. Harris (NIAID) and Dustin McCraw (NIAID).

*Intellectual Property:* HHS Reference No. E-005-2017—U.S. Provisional Application No. 62/540,474, filed August 2, 2017; PCT Application No. PCT/US2018/045032, filed August 2, 2018; United States Application No. 16/635,240, filed January 30, 2020 (pending); European Application No. 18756111.3, filed August 2, 2018 (pending); Chinese Application No. 201880063622.5, filed August 2, 2018 (pending); and Indian Application No. 202017008138, August 2, 2018 (pending).

*Licensing Contact:* To license this technology, please contact Elizabeth Pitts, Ph.D., 240-669-5299; [elizabeth.pitts@nih.gov](mailto:elizabeth.pitts@nih.gov).

Dated: March 18, 2021.

#### Surekha Vathyam,

*Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

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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: The Development of Natural Killer (NK) Cell Kita-Kyushu Lung Cancer Antigen 1 (KK-LC-1) T Cell Receptor (TCR) Therapy for the Treatment of KK-LC-1 Expressing Human Cancers

**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 Zelluna Immunotherapy (Zelluna), located in Oslo, Norway.

**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 April 14, 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: Abritee Dhal, Ph.D., Technology Transfer Manager, at Telephone: (240) 276-6154 or at Email: [abritee.dhal@nih.gov](mailto:abritee.dhal@nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Intellectual Property

U.S. Provisional Patent Application 62/327,529 entitled “Anti-KK-LC-1 T Cell Receptors” [HHS Ref. E-153-2016-0-US-01], PCT Patent Application PCT/US2017/027865 entitled “Anti-KK-LC-1 T Cell Receptors” [HHS Ref. E-153-2016-0-PCT-02], Australian Patent Application 2017258745 entitled “Anti-KK-LC-1 T Cell Receptors” [HHS Ref. E-153-2016-0-AU-03], Canadian Patent Application 3021898 entitled “Anti-KK-LC-1 T Cell Receptors” [HHS Ref. E-153-2016-0-CA-04], European Patent Application 1733120.4 entitled “Anti-KK-LC-1 T Cell Receptors” [HHS Ref. E-153-2016-0-EP-05], United States Patent Application 16/096,118, entitled “Anti-KK-LC-1 T Cell Receptors” [HHS Ref. E-153-2016-0-US-06], and U.S. and foreign patent applications claiming priority to the aforementioned applications.

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 development, manufacture and commercialization of a T-Cell Receptor (TCR) Therapy for the treatment of Kita-Kyushu Lung Cancer Antigen 1 (KK-LC-1) expressing cancers, using modified or unmodified natural killer (NK) cells transduced using viral vectors (including lentivirus or retrovirus) to express an anti-KK-LC-1 TCR wherein:

(1) The TCR has:

(a) A single antigen specificity; and

(b) a binding domain with complementary determining region (CDR) sequences of CASSLGTGGYNEQFF (beta chain) and CAGQLVYGNKLVF (alpha chain); and

(2) The modified allogeneic NK cells can be modified to express one or more of the following:

(a) CD3 subunits;

(b) CD8 co-receptor subunits;

(c) truncated CD34 tag;

(d) a chemokine receptor; or

(e) IL15.

For the sake of clarity, unmodified NK cells would mean cells that are modified only by the expression of the TCR without any additional modification.

This technology discloses TCRs that are specific for the cell surface domain of KK-LC-1. KK-LC-1 is a cancer germline antigen, that in adults, is reported to be expressed only by germ cells and by certain cancers, including gastric cancer, triple-negative breast cancer, and non-small cell lung cancer. Currently, there for no effective immunotherapies for patients with these various solid tumors. The NK-TCRs can potentially be used for the treatment of triple negative breast cancer, gastric cancer, and lung cancer. In the subject situation, the TCRs can lead to the selective destruction of the cancerous cells. The development of a new therapeutic targeting KK-LC-1 will benefit public health by providing an effective treatment for patients with solid tumors.

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: March 11, 2021.

**Richard U. Rodriguez,**

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

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2021-0178]

#### Consolidation of Redundant Coast Guard Boat Stations—Decision

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of decision.

**SUMMARY:** On February 14, 2020, the Coast Guard announced the potential consolidation of several redundant Coast Guard boat stations and solicited public comments to inform the decision making process. After reading the public comments, the Coast Guard has decided to consolidate four (4) Coast Guard boat stations to increase staffing and capacity levels at nearby boat stations that are better equipped to respond to calls for rescue.

**FOR FURTHER INFORMATION CONTACT:** For information about this document call or email Todd Aikins, Coast Guard Office of Boat Forces; telephone 202-372-2463, email [todd.r.aikins@uscg.mil](mailto:todd.r.aikins@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### Background and Purpose

This notice is issued under authority of 14 U.S.C. 909 and 910. The Coast Guard engaged in public outreach and connected with locals in the area of the boat stations to be closed. Opportunities were provided for a public meeting, but because of the pandemic it was decided that such collaboration was better done virtually.

##### Response to Public Comments

The Coast Guard received 111 distinct public submissions in response to the **Federal Register** Notice. Five supported the consolidations, while 106 raised concerns (one of the five supporting

comments recommended consolidating a single station as a proof of concept).

In the following discussion, we summarize the reasons or information some commenters gave in support of their position or recommendation. After each summary, we state our response.

No comments were submitted with concerns about the consolidation of Station(small) Roosevelt Inlet.

No comments were submitted with concerns about the consolidation of Station(small) Salem.

Two comments were submitted with concerns about the consolidation of Station(small) Shark River. One comment noted that a fast response is needed in the area, while the other asked that the decision be postponed until after the local COVID stay-at-home orders were lifted. The Coast Guard complied with the latter comment, and is following the findings of contractor analyses and the referenced GAO report that finds the remaining response sufficient in this area, most notably from Station Manasquan Inlet, fewer than ten miles away.

Four comments were submitted with concerns about the consolidation of Station(small) Fishers Island. All comments noted the area near Race Rock Lighthouse and its treacherous current, necessitating a fast Coast Guard Response. The Coast Guard is following the findings of contractor analyses and the referenced GAO report that finds the remaining response sufficient in this area, most notably from Station New London, fewer than ten miles away.

One hundred comments were submitted with concerns about the consolidation of Station Oxford. Twenty comments were general in nature, stating that the station is important and should not be closed. 69 comments noted that the area near Station Oxford is heavily worked and traveled, local resources have limited crews and hours, and that response from Station Annapolis would take too long. Six comments noted that Station Oxford was necessary for local triathlons, regattas, and other races. Three comments noted that boat safety checks are crucial to limiting the number of mariners in distress in the area. One comment noted that Station Oxford is critical to LMR in Terrapin Cover. One commenter felt that the data used in the studies was outdated and took issue with the fact that only the Coast Guard Districts with the most redundancy were included in the analyses instead of every station. In response to these concerns, Station Oxford will be removed as a candidate for closure in FY21 and analyzed further.