

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152, MSC 7770, Bethesda, MD 20892, 301-435-1017, tdrgon@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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 22, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04581 Filed 2-27-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of m971 and m972 Chimeric Antigen Receptors (CARs) for the Treatment of B Cell Malignancies

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in (a) U.S. Patent Application 61/717,960 entitled "M971 Chimeric Antigen Receptors" [HHS Ref. E-291-2012/0-US-01], and (b) U.S. Patent Application 61/042,239 entitled "Human Monoclonal Antibodies Specific for CD22" [HHS Ref. E-080-2008/0-US-01], PCT Application PCT/US2009/124109 entitled "Human and Improved Murine Monoclonal Antibodies Against CD22" [HHS Ref. E-080-2008/0-PCT-02], US patent application 12/934,214 entitled "Human Monoclonal Antibodies Specific for CD22" [HHS Ref. E-080-2008/0-US-03], and all related continuing and foreign patents/patent applications for these technology families, to Neomune, Inc. The patent rights in these inventions have been assigned to 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:

Treatment of B cell malignancies that express CD22 on their cell surface using chimeric antigen receptors which contain the m971 or m972 antibody binding fragments.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 1, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; Email: lambertson@mail.nih.gov.

SUPPLEMENTARY INFORMATION: Chimeric antigen receptors (CARs) are engineered cell surface receptors which have been designed to target immune effector cells (such as a T cell) to certain cellular targets. CARs target diseased cells through antigen-specificity domain recognizes a protein that is preferentially expressed on the cells, and the immune effector cell proceeds to eradicate the diseased cells. Since there are a number of cell surface proteins that are preferentially expressed on cancer cells, CARs are potential therapeutic candidates in the treatment of cancer.

The specific CARs for which this exclusive license may be granted comprise a targeting domain which contains the antibody binding fragments of the anti-CD22 antibodies m971 and m972. CD22 is a cell surface protein that is preferentially expressed on several types of cancer cells, including hematological malignancies such as chronic lymphocytic leukemia (CLL), acute lymphocytic leukemia (ALL), hairy cell leukemia (HCL) and non-Hodgkin's lymphoma (NHL). By linking an anti-CD22 antibody binding fragment to a CAR, it is possible to selectively kill the CD22-expressing cancer cells, leaving non-cancer cells alone. This results in an effective therapeutic strategy with fewer side effects than a non-targeted therapy.

The prospective exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless the NIH 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 404.7 within

thirty (30) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February 22, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013-04585 Filed 2-27-13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2011-1156]

Guidance Regarding Inspection and Certification of Vessels Under the Maritime Security Program

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of Navigation and Vessel Inspection Circular (NVIC) 01-13, "Inspection and Certification of Vessels Under the Maritime Security Program (MSP)." The MSP serves as a means for establishing a fleet of commercially viable and militarily useful vessels to meet national defense as well as other security requirements. NVIC 01-13 sets forth the Coast Guard's policies and procedures regarding the inspection and certification of vessels under the MSP. NVIC 01-13 provides a comprehensive approach to the MSP inspection process through the establishment of two levels of MSP inspection and oversight.

DATES: NVIC 01-13 is effective as of February 28, 2013.

ADDRESSES: To view the documents mentioned in this notice, go to <http://www.regulations.gov> and use "USCG-2012-1156" as your search term. Locate this notice in the search results, and use the filters on the left side of the page to locate specific documents by type. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through

Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Mr. John Hannon, Domestic Vessels Division, U.S. Coast Guard; telephone 202-372-1222, email John.J.Hannon@uscg.mil. If you have questions on viewing material in the docket, call Docket Operations at 202-366-9826.

SUPPLEMENTARY INFORMATION:

Viewing the NVIC and other documents: To view NVIC 01-13 and related documents, go to <http://www.regulations.gov>, use "USCG-2011-1156" as your search term, and follow the instructions in the **ADDRESSES** section above.

Background and Purpose

Title VI of the Merchant Marine Act of 1936, as amended by the Maritime Security Act of 1996 (MSA) (Pub. L. 104-239), authorized the establishment of a Maritime Security Fleet under the Maritime Security Program (MSP). The MSP serves as a means for establishing a fleet of commercially viable and militarily useful vessels to meet national defense as well as other security requirements.

The U.S. Maritime Administration (MARAD) Office of Sealift Support is the lead governmental office responsible for administration of the MSP. MARAD, in coordination with the Department of Defense, established a program whereby certain categories of militarily useful commercial vessels may be designated for emergency service to carry military cargo in time of war, national emergency, or military contingency. Some vessels enrolled in the MSP may receive a payment as part of their enrollment. Alternatively, vessels may enroll in other voluntary sealift support programs established by MARAD.

Section 53102(e) of Title 46 U.S.C. established standards for issuance of a Coast Guard Certificate of Inspection (COI) to a previously foreign-flagged vessel transitioning to U.S.-flagged once eligibility for the MSP has been established by MARAD and the Coast Guard. The statute does not specify the scope or manner of the inspections to be carried out by the Coast Guard to verify that MSP vessels fulfill requirements necessary to receive and maintain a COI.

The purpose of NVIC 01-13 is to provide the marine industry and Coast Guard personnel with uniform guidance regarding the MSP. Vessels that meet MSP enrollment criteria may obtain a COI by following the processes outlined in NVIC 01-13.

On January 19, 2012, the Coast Guard published a notice in the **Federal Register** announcing the availability of a draft NVIC 01-13 and requesting public comments on the draft (*See* 77 FR 2741). The Coast Guard recognized the need to avoid the inconsistent application of inspection procedures under the MSP. Accordingly, draft NVIC 01-13 outlined the inspection process for vessels transitioning from foreign-flag to U.S.-flag to obtain initial and ongoing certification under the MSP. To promote consistency and standardization of Coast Guard policies and procedures, draft NVIC 01-13 set forth a comprehensive approach to the MSP inspection process through the establishment of two levels of MSP inspection and oversight: (1) MSP (Regular); and (2) MSP Select. This two-level approach would enable the Coast Guard to apply traditional inspection methods to newly reflagged vessels, while at the same time apply a less stringent level of oversight to vessels that have consistently demonstrated satisfactory performance and substantial compliance with applicable rules. Newly enrolled MSP vessels would continue to be inspected by the Coast Guard in a manner similar to traditional Coast Guard inspections. After a period of evaluation, MSP vessels would be eligible to seek enrollment under MSP Select. MSP Select vessel oversight would consist of risk-based vessel examinations, periodic oversight, and evaluations of Authorized Class Society (ACS) survey activities.

We received eight public comment letters in response to the January 19, 2012 **Federal Register** notice. These comment letters contained a total of approximately 60 specific recommendations, suggestions, and other comments. We have created a document that provides a summary of each comment and the corresponding Coast Guard response. A copy of this public comment matrix is available for viewing in the public docket for this notice. You may access the docket going to <http://www.regulations.gov>, using "USCG-2011-1156" as your search term, and following the instructions in the **ADDRESSES** section above.

The basic framework of draft NVIC 01-13 described above is retained in the final version. The Coast Guard has made some changes from the draft version of NVIC 01-13 to the final version based on the public comments. A brief discussion of the most important changes is provided below. For more detailed information, please consult the actual public comment letters and public comment matrix in the docket.

(1) One commenter requested that we relax the standards for enrollment into the MSP Select Program by evaluating the ship operating company's regulatory compliance record over the most recent 5-year period. The commenter suggested that if the operator is found to be fully compliant during that period, all of its vessels should be permitted to enroll in MSP Select. We disagree. We believe that a vessel-specific approach is more appropriate for sufficiently and effectively evaluating regulatory compliance. While we disagree with the commenter's approach, we have decided to reduce the performance verification period from 5 years to 3 years in order to lessen the burden on vessel operators.

(2) In response to a commenter's request, we provided more detail regarding Marine Inspector requirements, requisite qualifications, and duties associated with the MSP. We have added the requested language in Sections 2.2.1. and 2.2.2. of NVIC 01-13.

(3) We received a number of comments pertaining to engine automation, the applicability of Engine International Air Pollution Prevention (EIAPP) certificates, and the procedures for underwater survey in lieu of drydocking (UWILD). In response to these comments, we provided additional clarification regarding vessel automation approval, EIAPP certification, and UWILD procedures.

This notice is issued under authority of 5 U.S.C. 552(a), 46 U.S.C. 53102(e), and Department of Homeland Security Delegation No. 0170.1(1).

Dated: February 22, 2013.

Paul F. Thomas,

Captain, U.S. Coast Guard, Director, Inspections and Compliance.

[FR Doc. 2013-04732 Filed 2-27-13; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R4-R-2012-N154;
FXRS1265040000S3-123-FF04R02000]

Clarks River National Wildlife Refuge, KY; Final Comprehensive Conservation Plan/Land Protection Plan, and Finding of No Significant Impact for the Environmental Assessment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the Fish and Wildlife Service (Service), announce the