

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]

BILLING CODE 4140-01-P

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.

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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