[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Anti-CD22 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 Part 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 61/549,516 entitled "Anti-CD22 Chimeric Antigen Receptors" [HHS Ref. E-265-2011/0-US-01], and (b) U.S. Patent Application 60/325,360 [HHS Ref. E-129-2001/0-US-01], PCT Application PCT/US02/30316 [HHS Ref. E-129-2001/0-PCT-02], U.S. Patent 7,355,012 [HHS Ref. E-129-2001/0-US-03], European Patent 1448584 [HHS Ref. E-129-2001/0-EP-04] (validated in Germany, Spain, France, The United Kingdom and Italy [HHS Ref. E-129-2001/0-IT-12], Australian Patent 2002327053 [HHS Ref. E-129-2001/0-AU-05], Canadian Patent Application 2461351 [HHS Ref. E-129-2001/0-CA-06], U.S. Patent 7,777,019 [HHS Ref. E-129-2001/0-US-07], U.S. Patent Application 12/846,625 [HHS Ref. E-129-2001/0-US-13], U.S. Patent Application 13/438,725 [HHS Ref. E-129-2001/0-US-14] (all entitled "Mutated Anti-CD22 Antibodies with Increased Affinity to CD22 Expressing Leukemia Cells"), 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 HA22 or BL22 antibody binding fragments.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: 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; E-mail: lambertsond@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 HA22 and

BL22. 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 Part 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 Part 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.

October 9, 2012
Date

_____

Richard U. Rodriguez,
Director
Division of Technology Development & Transfer
Office of Technology Transfer
National Institutes of Health

[FR Doc. 2012-25187 Filed 10/12/2012 at 8:45 am; Publication Date: 10/15/2012]