[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Chimeric Antigen Receptors Targeting B-cell Maturation Antigen to Treat or Prevent Cancer and Autoimmune Disease

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Bluebird Bio to practice the inventions embodied in US Provisional Patent Application Serial No. 61/622,600, entitled "Chimeric Antigen Receptors Targeting B-cell Maturation Antigen" [HHS Ref. E-040-2012/0-US-01], and International (PCT) Application No. PCT/US13/32029, entitled "Chimeric Antigen Receptors Targeting B-cell Maturation Antigen" [HHS Ref. E-040-2012/0-PCT-02], and all continuing applications and foreign counterparts. The patent rights in these inventions have been assigned 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:

> Use of the Patent Rights to make and have made, to sell, to offer for sale, to import, and to use in humans, human autologous peripheral blood T-cells modified by recombinant human immunodeficiency virus ("HIV")-based lentiviral vectors or murine leukemia virus ("MLV")-based gamma-retroviral vectors to express chimeric antigen receptors that recognize B-cell Maturation Antigen ("BCMA") for the treatment or prevention of cancer and autoimmune diseases.

DATES: Only written comments or applications for a license (or both) 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.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Patrick McCue, Ph.D., 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: mccuepat@od.nih.gov.

SUPPLEMENTARY INFORMATION: These inventions concern a series of chimeric antigen receptors (CARs) that specifically target BCMA, a protein that is highly expressed on the surface of multiple myeloma cells. The pending patent application includes claims to compositions and vectors incorporating the CARs, as well as methods of destroying multiple myeloma cells using T-cells engineered to express a CAR.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. 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 within thirty (30) days from the date of this published notice.

Applications for a license in the field of use that are 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: July 14, 2014.

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Richard U. Rodriguez, M.B.A.,
Director,
Division of Technology Development and Transfer,
Office of Technology Transfer,
National Institutes of Health.

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