[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License Agreement: Development of Bispecific and Multi-specific Fusion Proteins for the Treatment of ROR1 Expressing Human Cancers

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 license agreement to practice the inventions embodied in US Provisional Application No. 61/418,550 entitled, "Chimeric rabbit/human ROR1 antibodies" filed December 1, 2010 [HHS Ref. E-039-2011/0-US-01]; PCT Application No. PCT/US2011/062670 entitled, "Chimeric rabbit/human ROR1 antibodies" filed November 30, 2011 [HHS Ref. E-039-2011/0-PCT-02]; Australian Patent Application No. 2011336650 entitled, "Chimeric rabbit/human ROR1 antibodies" filed November 30, 2011 [HHS Ref. E-039-2011/0-AU-03]; Canadian Patent Application No. 2818992 entitled, "Chimeric rabbit/human ROR1 antibodies" filed November 30, 2011 [HHS Ref. E-039-2011/0-CA-04]; European Patent Application No. 11791733.6 entitled, "Chimeric rabbit/human ROR1 antibodies" filed November 30, 2011 [HHS Ref. E-039-2011/0-EP-05]; and U.S. Patent Application No. 13/990,977 entitled, "Chimeric rabbit/human ROR1 antibodies" filed May 31, 2013 [HHS Ref. E-039-2011/0-US-06] and all related

continuing and foreign patents/patent applications for the technology family to Emergent BioSolutions. 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 the use of the Licensed Patent Rights to develop, make, have made, sell, have sold, import and export bi-specific and multi-specific fusion proteins that are capable of eliciting redirected T-cell cytotoxicity for the treatment of human receptor tyrosine kinase-like orphan receptor 1(ROR1) expressing cancers, wherein said fusion proteins comprise one or more single-chain variable fragment (scFv) ROR1 binding domains from the anti-ROR1 antibodies designated as R11 or R12, one or more of Licensee's proprietary scFv CD3 binding domains, and optionally a fragment crystallizable (Fc) domain.

DATES: 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.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Jennifer Wong, M.S., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4633; Facsimile: (301) 402-0220; E-mail: wongje@od.nih.gov.

SUPPLEMENTARY INFORMATION: Tyrosine kinase-like orphan receptor 1 (ROR1) is a signature cell surface antigen for B-cell malignancies, most notably, B-cell chronic lymphocytic leukemia (B-CLL) and mantle cell lymphoma (MCL) cells, two incurable diseases. The investigators have developed a portfolio of chimeric anti-ROR1 monoclonal antibodies that

selectively target ROR1 malignant B-cells but not normal B-cells. These antibodies may be linked to chemical drugs or biological toxins thus providing targeted cytotoxic delivery to malignant B-cells while sparing normal cells. Moreover, as these antibodies selectively target ROR1, they can also be used to diagnose B-cell malignancies.

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

Any additional, properly filed, and 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: June 22, 2015.

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

[FR Doc. 2015-15655 Filed: 6/25/2015 08:45 am; Publication Date: 6/26/2015]