[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive Commercialization License: Anti-tyrosine Kinase-like Orphan Receptor 1 Immunotoxins for the Treatment of 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 a start-up exclusive commercialization license to practice the inventions embodied in U.S. Patent Application 61/172,099 entitled "Anti-human ROR1 Antibodies" [HHS Ref. E-097-2009/0-US-01], U.S. Patent Application No. 13/990,977 entitled, "Chimeric Rabbit/Human ROR1 Antibodies" filed June 7, 2013 [HHS Ref. No. E-039-2011/0], U.S. Patent Application 60/703,798 entitled "Mutated Pseudomonas Exotoxins with Reduced Antigenicity" [HHS Ref. E-262-2005/0-US-01], U.S. Patent Application 60/969,929 entitled "Deletions in Domain II of Pseudomonas Exotoxin A that Remove Immunogenic Epitopes with Affecting Cytotoxic Activity" [HHS Ref. E-292-2007/0-US-01], U.S. Patent Application 61/241,620 entitled "Improved Pseudomonas Exotoxin A with Reduced Immunogenicity" [HHS Ref. E-269-2009/0-US-

01], U.S. Patent Application 61/483,531 entitled "Recombinant Immunotoxin Targeting Mesothelin" [HHS Ref. E-117-2011/0-US-01], U.S. Patent Application 61/495,085 entitled "Pseudomonas Exotoxin A with Less Immunogenic T-Cell/or B-Cell Epitopes" [HHS Ref. E-174-2011/0-US-01], U.S. Patent Application 61/535,668 entitled "Pseudomonas Exotoxin A with Less Immunogenic B-Cell Epitopes" [HHS Ref. E-263-2011/0-US-01], and any PCT, US or foreign applications claiming benefit of the technology families, to Magnifygen, Inc. 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 development and use of immunotoxins comprising an anti-tyrosine kinase-like orphan receptor 1 monoclonal antibody designated as 2A2, R11, R12, or Y31 and *Pseudomonas* exotoxin A for the treatment of human cancers as claimed within the scope of the Licensed Patent Rights. For avoidance of doubt, the Licensed Field of Use excludes the development of antibody-drug conjugates and bispecific antibodies comprising said antibodies.

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 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive 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: This invention concerns anti-ROR1immunotoxin comprising an anti-ROR1antibody designated as 2A2, R11, R12 or Y31 and *Pseuodomonas* Exotoxin A (PE) as treatment for human ROR1 expressing cancers. The immunotoxin will comprise a chimeric mouse anti-human receptor tyrosine kinase-like orphan receptor 1 monoclonal antibody whereas the immunotoxin will have a toxin domain derived from PE. PE toxin's domain have been modified in various ways in order to reduce the immunogenicity of the molecule to improve its therapeutic value while at the same time maintaining the toxin's ability to trigger cell death. The immunotoxin provides targeted cytotoxic delivery to cancer cells while sparing normal cells thereby resulting in therapies with fewer side effects.

The prospective start-up exclusive commercialization license is being considered under the small business initiative launched on October 1, 2011 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 fifteen (15) days from the date of this published notice.

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: December 19, 2014

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

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