This document is scheduled to be published in the
Federal Register on 04/09/2013 and available online at
http://federalregister.gov/a/2013-08148, and on **FDsys.gov**

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of An Exclusive Evaluation Option License: Pre-clinical Evaluation of 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(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 U.S. Patent Application 61/172,099 entitled "Anti-human ROR1 Antibodies" [HHS Ref. E-097-2009/0-US-01], 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 all related continuing and foreign patents/patent applications for the technology family, to SPEED BioSystems, LLC. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to pre-clinical evaluation of lead therapeutic candidates for the development and use of anti-tyrosine kinase-like orphan receptor 1 (ROR1) targeted immunotoxins for the treatment of human ROR1 expressing cancers, wherein the immunotoxin comprises an anti-ROR1 antibody designated as 2A2 and *Pseudomonas* exotoxin A (PE). Upon expiration or termination of the exclusive evaluation option license, SPEED will have the right to execute an exclusive patent commercialization license which will supersede and replace the exclusive evaluation option license with no broader territory than granted in the exclusive evaluation option license and the field of use will be commensurate with the commercial development plan at the time of conversion.

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 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: This invention concerns anti-ROR1 immunotoxin comprising an anti-ROR1 antibody designated as 2A2 and PE as a 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 exclusive evaluation option license is being considered under the small business initiative launched on October 1, 2011and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive evaluation option license, and a subsequent exclusive patent commercialization license, may be granted unless within fifteen (15) 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 404.7.

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 evaluation option 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.

April 2, 2013
Date

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

[FR Doc. 2013-08148 Filed 04/08/2013 at 8:45 am; Publication Date: 04/09/2013]