[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Evaluation License: Development of Antibody-Drug Conjugates Comprising Topoisomerase Inhibitors 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 an exclusive license to practice the inventions embodied in US Provisional Patent Application No. 60/844,027 entitled, "Azonafide derived tumor and cancer targeting compounds," filed September 12, 2006 [HHS Ref. No. E-160-2006/0-US-01], PCT Application No. PCT/US2007/078233 entitled, "Azonafide derived tumor and cancer targeting compounds," filed September 12, 2007 [HHS Ref. No. E-160-2006/0-PCT-02], European Patent Application No. 7842310.0 entitled, "Azonafide derived tumor and cancer targeting compounds," filed September 12, 2007 [HHS Ref. No. E-160-2006/0-EP-03], and U.S. Patent Application No. 12/441,029 entitled, "Azonafide derived tumor and cancer targeting compounds," filed March 12, 2009 now US Patent No. 8,008,316 issued August 30, 2011 [HHS Ref. No. E-160-2006/0-US-04], and all related continuing and foreign patents/patent applications for the technology family, to Oncolinx, Inc. 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 the development and use of the licensed patent rights as a component of an antibody-drug conjugate for the treatment of human cancers. Upon expiration or termination of the exclusive evaluation option license, Oncolinx 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.

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 15 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: The present technology provides compound formulation and method of use of improved derivatives of 2-[2'-(2-aminoethyl)-2-methyl-ethyl]-l,2-dihydro-6-methoxy-3H-dibenz-[de,h]isoquinoline-l,3-dione (herein referred to as azonafides), anthracene-based DNA intercalcators that inhibit tumor growth. The synthesized azonafides can be attached to a ligand or antibody to recognize specific receptors on cancer cells and delivered as a targeted cytotoxic payload. The azonafides have been developed to allow for easy modification with different peptide linkers and antibodies, but also allow for rapid release once cleaved in

lysosomes after delivery to the cancer cell enabling highly targeted attack of cancer cells. The azonafides have reduced toxicity and lower development of drug resistance.

The prospective exclusive evaluation option 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 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.

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.

Dated: September 9, 2014.

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

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