[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Use of Agents Targeting Thrombospondin-1 and CD47 to Treat Radiation-Induced Damage and Enhance the Effectiveness of Radiotherapy in Cancer Patients

AGENCY: National Institutes of Health, Public Health Service, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a worldwide exclusive license, to practice the inventions embodied in U.S. Provisional Patent Application No. 60/850,132, filed October 6, 2006, now abandoned (HHS Ref. No. E-227-2006/0-US-01); U.S. Provisional Patent Application No. 60/864,153, filed November 02, 2006, now abandoned (HHS Ref. No. E-227-2006/1-US-01); U.S. Provisional Patent Application No. 60/888,754, filed February 07, 2007, now abandoned (HHS Ref. No. E-227-2006/2-US-01); U.S. Provisional Patent Application No. 60/910,549, filed April 06, 2007, now abandoned (HHS Ref. No. E-227-2006/3-US-01); U.S. Provisional Patent Application No. 60/956,375, filed August 16, 2007, now abandoned (HHS Ref. No. E-227-2006/4-

US-01); PCT Patent Application No. PCT/2007/080647, filed October 5, 2007, now abandoned (HHS Ref. No. E-227-2006/5-PCT-01); U.S. Patent Application No. 12/444,364, filed April 3, 2009 (HHS Ref. No. E-227-2006/5-US-02); Canadian Patent Application No. 2,665,287, filed October 5, 2007 (HHS Ref. No. E-227-2006/5-CA-03); Australian Patent Application No. 2007319576, filed October 5, 2007 (HHS Ref. No. E-227-2006/5-AU-04); European Patent Application No. 07868382.8, filed October 5, 2007 (HHS Ref. No. E-227-2006/5-EP-05); U.S. Provisional Patent Application No. 61/086,991, filed August 7, 2008, now abandoned (HHS Ref. No. E-153-2008/0-US-01); PCT Patent Application No. PCT/2009/052902, filed August 5, 2009, now abandoned (HHS Ref. No. E-153-2008/0-PCT-02); U.S. Patent Application No. 13/057,447, filed February 3, 2011 (HHS Ref. No. E-153-2008/0-US-06); Canadian Patent Application No. 2732102 filed August 5, 2009 (HHS Ref. No. E-153-2008/0-CA-043); Australian Patent Application No. 2009279676, filed August 5, 2009 (HHS Ref. No. E-153-2008/0-AU-03); and European Patent Application No. 09791202.6, filed August 5, 2009 (HHS Ref. No. E-153-2008/0-EP-08), entitled "Prevention of Tissue Ischemia, Related Methods and Compositions," and "Radioprotectants Targeting Thrombospondin-1 and CD47," to Radiation Control Technologies, Inc., a company incorporated under the laws of the State of Delaware having its headquarters in Rockville, Maryland. The United States of America is the assignee of the rights of the above inventions. The prospective exclusive license territory may be "worldwide," and the field of use may be limited to: 1) the use of morpholino oligonucleotides that reduce expression of CD47 in combination with radiotherapy, to treat or prevent cancers in humans; and 2) the use of morpholino

oligonucleotides that reduce expression of CD47 to treat or prevent radiation exposure damage in humans.

DATE: Only written comments and/or applications for a license 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.

ADDRESS: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Suryanarayana (Sury) Vepa, Ph.D., J.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5020; Facsimile: (301) 402-0220; E-mail: vepas@mail.nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The present inventions provide for compositions and methods for preventing and/or reducing tissue ischemia and/or tissue damage due to ischemia, increasing blood vessel diameter, blood flow and tissue perfusion in the presence of vascular disease, by suppressing CD47 and/or blocking TSP1 and/or CD47 activity or interaction. The present inventions also provide for the use of morpholinos, peptides and antibodies that block the TSP1/CD47 signaling pathway as

radioprotectants for normal tissue, radioenhancers for tumor tissue, and as protectants of normal tissue from damage caused by radiation exposure.

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 404.7. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published notice, 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 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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.

December 2, 2011
Date

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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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