

and Hematology Research, National Institutes of Health, HHS)

Dated: October 4, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-26215 Filed 10-11-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Secreted Frizzled Related Protein-1 (sFRP-1) and derivatives thereof and their Use In Therapeutic Applications

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

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 patent license to practice the inventions embodied in the patents and patent applications belonging to the patent families having HHS Reference Numbers E-160-1997/0, /1, /2 and /3; E-014-2000/0; and E-060-2000/0, and /1. Specific details regarding the individual patents or patent applications which belong to these patent families are set forth in the table below:

Patent application number	Country	Filing date or international filing date	Status	Publication or patent number
60/050,417	US	5/29/1997	Abandoned	N/A
60/050,495	US	6/23/1997	Abandoned	N/A
09/087,031	US	5/29/1998	Issued	6,479,255
10/138,434	US	5/3/2002	Issued	7,183,377
PCT/US98/10974	PCT	5/29/1998	Expired	WO 98/54325
09/546,043	US	4/10/2000	Issued	6,600,018
10/425,586	US	4/28/2003	Issued	7,223,853
11/748,872	US	5/15/2007	Issued	7,947,651
13/031,060	US	2/18/2011	Pending	N/A
60/260,908	US	1/10/2001	Abandoned	N/A
PCT/US02/00869	PCT	1/10/2002	Expired	WO 02/055547
10/466,136	US	7/10/2003	Issued	7,488,710
12/019,567	US	1/24/2008	Pending	20080145884 A1
2002241859	AU	1/10/2002	Issued	2002241859
2,434,672	CA	1/10/2002	Pending	2,434,672
02 707454.1	EP	1/10/2002	Pending	1387854 A2
2002-556615	JP	1/10/2002	Issued	4029041
2007-120533	JP	1/10/2002	Issued	4248583
2008-169716	JP	1/10/2002	Issued	4248600

to Achelois BioSciences, Inc., a Delaware corporation having a place of business in Lexington, Massachusetts. The patent rights in these inventions have been assigned to the United States of America. In addition, the all of the rights associated with applications 09/546,043; 10/425,586; 11/748,872 and 13/031,060 are exclusively licensed to HHS by the co-owner the University of Massachusetts.

The prospective exclusive license territory may be "worldwide", and the field of use may be limited to "use of sFRP-1 and derivatives thereof in the treatment of human disease."

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before November 14, 2011 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Susan S. Rucker, JD, CLP, Senior Advisor for Intellectual Property Transactions, Office of

Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4478; Facsimile: (301) 402-0220; E-mail: ruckersu@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The technology encompassed by the patents and/or patent applications (IP) to be included in this exclusive license relates to a protein designated secreted Frizzled Related Protein-1 (sFRP-1). sFRP-1, also known as SARP-2 (Secreted Apoptosis Related Protein-2). The IP covers various sFRP-1 compositions and uses thereof.

sFRP-1 is associated with Wnt signaling which has been implicated in a number of different processes including fibrosis (see, Hwang, I *et al.* Arch Pharm Res 32(12): 1653-62 (2009)) and bone remodeling (see, Hausler KD *et al* J Bone Miner Res 19(11) 1873-81 (Nov 2004). In addition, hypermethylation of the sFRP-1 promoter region, which leads to a loss of function and decreased sFRP-1 protein expression, has been linked to a

number of cancers, including gastric cancer, esophageal adenocarcinoma, bladder cancer and head and neck squamous cell carcinoma (HNSCC).

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 part 404.7. The prospective 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 404.7.

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: October 4, 2011.

Richard U. Rodriguez,

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

[FR Doc. 2011-26343 Filed 10-11-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Human Anti-Mesothelin Monoclonal Antibodies for the Treatment of Human Cancers

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 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 patent license to practice the inventions embodied in U.S. Patent Application 61/040,005 entitled "Human Monoclonal Antibodies Specific for Mesothelin" [HHS Ref. E-079-2008/0-US-01], PCT Application PCT/US2009/038228 entitled "Human Monoclonal Antibody Against Mesothelin" [HHS Ref. E-079-2008/0-PCT-02], Australian patent application AU 2009228361 entitled "Human Monoclonal Antibody Against Mesothelin" [HHS Ref. E-079-2008/0-AU-03], Canadian patent application CA 2718321 entitled "Human Anti-Mesothelin Monoclonal Antibodies" [HHS Ref. E-079-2008/0-CA-04], European patent application EP 09726082.2 entitled "Human Monoclonal Antibody Against Mesothelin" [HHS Ref. E-079-2008/0-EP-05], U.S. patent application 12/934,060 entitled "Human Anti-Mesothelin Monoclonal Antibodies" [HHS Ref. E-079-2008/0-US-06], and all related continuing and foreign patents/patent applications for the technology family, to Sanomab, Ltd. The patent rights in these inventions have been assigned to and/or exclusively licensed 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 monoclonal antibody m912 (SM-101) as an antibody therapy for the treatment of pancreatic cancer, ovarian cancer, lung cancer, mesothelioma, and stomach/gastric cancer. The Licensed Field of Use explicitly excludes the use of the

antibody in the form of an immunoconjugate, including, but not limited to, immunotoxins.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before November 14, 2011 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; *Telephone:* (301) 435-4632; *Facsimile:* (301) 402-0220; *E-mail:* lambertsond@od.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns a monoclonal antibody and methods of using the antibody for the treatment of mesothelin-expressing cancers, including mesothelioma, lung cancer, stomach/gastric cancer, ovarian cancer and pancreatic cancer. The specific antibody covered by this technology is designated m912 (SM-101), which is a fully human monoclonal antibody against mesothelin.

Mesothelin is a cell surface antigen that is preferentially expressed on certain types of cancer cells. The m912 antibody can selectively bind to these cancer cells and induce cell death while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells. 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 part 404.7. 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 404.7 within thirty (30) days from the date of this published notice.

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: October 4, 2011.

Richard U. Rodriguez,

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

[FR Doc. 2011-26342 Filed 10-11-11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4031-DR; Docket ID FEMA-2011-0001]

New York; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of New York (FEMA-4031-DR), dated September 13, 2011, and related determinations.

DATES: *Effective Date:* September 13, 2011.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 13, 2011, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of New York resulting from the Remnants of Tropical Storm Lee beginning on September 7, 2011, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of New York.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved