

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel; National Research Service Award Institutional Research Training Grants.

Date: October 20, 2010.

Time: 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Weiqun Li, MD, Scientific Review Administrator, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Ste. 710, Bethesda, MD 20892, (301) 594-5966, wli@mail.nih.gov.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel; Informed-Decision Making in Young Adolescent At-Risk for HIV/AIDS.

Date: November 2, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Mario Rinaudo, MD, Scientific Review Officer, Office of Review, National Inst of Nursing Research, National Institutes of Health, 6701 Democracy Blvd (DEM 1), Suite 710, Bethesda, MD 20892, 301-594-5973, mrinaudo@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. (Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: September 8, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-22832 Filed 9-13-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel, Clinical Trial Review.

Date: October 14, 2010.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Tamizchelvi Thyagarajan, PhD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd, Rm. 710, Bethesda, MD 20892, (301) 594-0343, tamizchelvi.thyagarajan@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: September 8, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-22831 Filed 9-13-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of AAV5 Based Therapeutics To Treat Human Diseases

AGENCY: National Institutes of Health, Public Health Service, DHHS.

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 invention embodied in U.S. Patent 6, 984, 517, entitled "AAV5 and Uses Thereof," U.S. Patent 7, 479, 554, entitled "AAV5 Nucleic Acids" and PCT Application Serial No. PCT/US99/11958 and foreign equivalents thereof, entitled "AAV5 and Uses Thereof" [HHS Ref. No. E-127-1998/0]; and U.S. Patent 6, 855, 314 entitled "AAV5 Vector for Transducing Brain Cells and Lung Cells" [HHS Ref. No. E-072-2000/0] to Amsterdam Molecular Therapeutics, which is located in Amsterdam, The Netherlands. The Government of the United States of America has the right to license these patent rights.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the development and sale of AAV5 based therapeutic products to be delivered to the brain, eyes and liver for treatment of diseases originated from these organs, as claimed in the Licensed Patent Rights.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before October 14, 2010 will be considered.

ADDRESSES: Requests for copy of the patent, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Betty B. Tong, PhD., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 594-6565; Facsimile: (301) 402-0220; E-mail: tongb@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The technology describes an adeno-associated virus 5 (AAV5), vectors and particles derived from the virus; as well as methods of delivering nucleic acids to a cell by using the AAV5 vectors and particles. More specifically, the

technology provides the methods of delivering nucleic acids to cells of specific regions, tissues and cell types of the central nervous system (CNS); as well as to cells of the lung, by using AAV5 vectors and particles. The specific brain cells that are targeted by AAV5 belong to both non-neuronal/glia cells and neuronal cells, such as cerebellar cells and ependymal cells. The specific lung cells targeted by AAV5 are the apical surfaces of the airway such as alveolar 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 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 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: September 7, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010-22833 Filed 9-13-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Immunotoxins/Targeted Toxins for the Treatment of Human Cancers

AGENCY: National Institutes of Health, Public Health Service, DHHS.

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, 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 61/241,620 entitled "Development of an Immunotoxin in Which All B-Cell Epitopes Have Been Removed and

Which Has High Cytotoxic Activity" [HHS Ref. E-269-2009/0-US-01], U.S. Patent Application 60/969,929 entitled "Deletions in Domain II of Pseudomonas Exotoxin A That Reduce Non-Specific Toxicity" [HHS Ref. E-292-2007/0-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 60/160,071 entitled "Immunoconjugates Having High Binding Affinity" [HHS Ref. E-139-1999/0-US-01], U.S. Patent Application 60/067,175 entitled "Antibodies, Including Fv Molecules, and Immunoconjugates Having High Binding Affinity for Mesothelin and Methods for Their Use" [HHS Ref. E-021-1998/0-US-01], U.S. Patent Application 60/010,166 entitled "Molecular Cloning of Mesothelin, a Differentiation Antigen Present on Mesothelium, Mesotheliomas and Ovarian Cancers" [HHS Ref. E-002-1996/0-US-01], PCT Application PCT/US97/00224 entitled "Mesothelin Antigen and Methods and Kits for Targeting It" [HHS Ref. E-002-1996/1-PCT-01], U.S. Patent 5,747,654 entitled "Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity" [HHS Ref. E-163-1993/0-US-01], PCT application PCT/US96/16327 entitled "Immunotoxin Containing A Disulfide-Stabilized Antibody Fragment" [HHS Ref. E-163-1993/2-PCT-01], U.S. Patent Application 07/596,291 entitled "A Monoclonal Antibody" [HHS reference E-195-1990/0-US-01], and all continuing applications and foreign counterparts, to Morphotek, Inc. 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 MORAb-009-PE-LR/8X immunotoxin for the treatment of mesothelin-expressing cancers, the use of the anti-CD300LF-PE/LR/8X immunotoxin for the treatment of CD300LF-expressing cancers such as acute myelogenous leukemia (AML), and the use of annexin A2-targeted PE-LR/8X toxin for the treatment of annexin A2-expressing cancers such as glioma, ovarian cancer and pancreatic cancer.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before October 14, 2010 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, PhD., 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: These inventions concern immunotoxins and targeted toxins, and methods of using the immunotoxins/targeted toxins for the treatment of (a) mesothelin-expressing cancers (such as mesothelioma, ovarian cancer and pancreatic cancer), (b) CD300LF-expressing cancers (such as acute myelogenous leukemia (AML)) or (c) Annexin A2-expressing cancers (such as glioma, ovarian cancer and pancreatic cancer). Several specific immunotoxins/targeted toxins are covered by this technology, including MORAb-009-PE-LR/8X, anti-CD300LF-PE-LR/8X and Annexin A2-targeted PE-LR/8X.

Each of these immunotoxins/targeted toxins comprises (1) a toxin moiety (PE-LR/8X) that is a modified version of the *Pseudomonas* exotoxin A ("PE") and (2) either (a) an antibody fragment domain that is capable of binding to mesothelin, (b) an antibody fragment domain that is capable of binding to CD300LF, or (c) a peptide that is capable of binding to Annexin A2. The toxin moiety been modified in various manners in order to reduce immunogenicity, thereby improving the therapeutic value of PE while maintaining its ability to trigger cell death. Since mesothelin, CD300LF and Annexin A2 are each preferentially expressed on certain types of cancer cells, the targeting domains of the immunotoxins/targeted toxins (MORAb-009, anti-CD300LF and Annexin A2 binding peptide) allows the immunotoxins/targeted toxins to selectively bind to certain cancer cells so that only the cancer cells are killed. This results 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 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 404.7 within thirty (30) days from the date of this published notice.

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.