

Dated: October 24, 2012.

Mary K. Wakefield,  
Administrator.

[FR Doc. 2012-26565 Filed 10-29-12; 8:45 am]

BILLING CODE 4165-15-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel, Dating Violence and Marketing.

*Date:* November 13, 2012.

*Time:* 1:00 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Anna L. Riley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301-435-2889, [rileyann@csr.nih.gov](mailto:rileyann@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 24, 2012.

David Clary,  
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-26602 Filed 10-29-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Ancillary Studies to the ISC Consortium.

*Date:* November 29, 2012.

*Time:* 3:30 p.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7637, [davila-bloomm@extra.niddk.nih.gov](mailto:davila-bloomm@extra.niddk.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 23, 2012.

David Clary,  
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-26603 Filed 10-29-12; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive Evaluation Option License: Pre-clinical Evaluation of Human Therapeutics Utilizing Ubiquitin Based Fusion Proteins With Apoptosis Modifying Proteins Such as BCL-X<sub>L</sub>

**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, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to practice the inventions covered under the scope of United States Patent No. 6,737,511 issued May 18, 2004 entitled "Receptor-mediated Uptake of an Extracellular BCL-x<sub>L</sub> Fusion Protein Inhibits Apoptosis" (HHS Ref. No. E-073-1999/0-US-02; Inventors Richard Youle et al.) and International Patent Application No. PCT/US2012/032762 filed April 9, 2012 entitled "Ubiquitin Fusions for Improving the Efficacy of Cytosolic Acting Targeted Toxins" (HHS Ref. No. E-150-2011/0-PCT-02; Inventors Christopher Bachran et al.) to Medicenna Therapeutics, ("MEDICENNA") a Canada based company. The patent rights in this invention 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 pre-clinical evaluation of lead therapeutic candidates for the development of human therapeutics within the field of cancer and neurological diseases. Upon expiration or termination of the exclusive evaluation option license, MEDICENNA 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 November 14, 2012 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A. Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5587; Facsimile: (301) 402-0220; Email: [chatterjeesa@mail.nih.gov](mailto:chatterjeesa@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The technologies covered under the present inventions relate to (1) apoptosis-modifying fusion proteins with at least two domains, one of which targets the fusion proteins to a target cell, and another of which modifies an apoptotic response of the target cell. For example, fusing various cell-binding domains to Bcl-X<sub>L</sub> and Bad allows targeting to specific subsets of cells *in vivo*, permitting treatment and/or prevention of cell-death related consequences of various diseases and injuries. This technology could be used to minimize or prevent apoptotic damage that can be caused by neurodegenerative disorders, e.g., Alzheimer's disease, Huntington's disease or spinal-muscular atrophy, stroke episodes or transient ischemic neuronal injury, e.g., spinal cord injuries. Additionally, apoptotic-enhancing fusion proteins of the current invention could be used to inhibit cell growth, e.g., uncontrolled cellular proliferation and (2) a platform technology using ubiquitin to improve the delivery and efficacy of cytosolic targeted toxins. This invention describes generation of fusion proteins via the introduction of the protein ubiquitin, a small protein in eukaryotic cells that plays a role in protein recycling, in between a targeting moiety and a catalytic moiety. Ubiquitin contains a cleavable motif at its C-terminus, which can help in the decoupling of the two moieties. Decoupling of the two moieties would increase the cytotoxicity of the treatment, since the catalytic domain of a Targeted Toxin (TT) remains longer in the cytosol. This method of generating fusion proteins would be highly useful for all TT and immunotoxins that access the cytosol to either affect cytosolic targets or traffic to further sites of action.

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 404.7. 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.

Dated: October 23, 2012.

**Richard U. Rodriguez,**

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

[FR Doc. 2012-26601 Filed 10-29-12; 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 Chemopreventive Treatments for Head and Neck Squamous Cell Carcinoma

**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, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to practice the inventions embodied in PCT Patent Application No. PCT/US2009/054478, U.S. Patent Application No. 13/059,335 and foreign equivalents thereof entitled "Chemopreventive of Head and Neck Squamous Cell Carcinoma" (HHS Ref. No. E-302-2008/0) and PCT Patent Application No. PCT/IL2010/000694, U.S. Patent Application No. 13/391,756 and foreign equivalents thereof entitled "Prevention and Treatment of Oral and Lips Diseases Using Sirolimus and Derivatives Sustained Release Delivery Systems for Local Application to the Oral Cavity" (HHS Ref. No. E-282-2009/0) to Rapamycin Holdings, Inc., which is located in San Antonio, TX. The patent rights in these inventions

have been assigned to the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to use of the Licensed Patent Rights for the prevention and treatment of head and neck cancers.

Upon the expiration or termination of the exclusive evaluation option license, Rapamycin Holdings, Inc. will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

**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, 2012 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: Whitney A. Hastings, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; Email: [hastingsw@mail.nih.gov](mailto:hastingsw@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** In head and neck squamous cell carcinoma (HNSCC), a cancer occurring mostly in the mouth, it is frequently observed that the Akt/mTOR pathway is abnormally activated. Therefore, inhibiting this signaling pathway may help in treating this disease. Rapamycin and its analogs are known to inhibit the activity of mTOR so in principle they could serve as therapeutics for treating HNSCC.

This technology describes a method of potentially preventing or treating HNSCC through the inhibition of mTOR activity. The proof of this principle was demonstrated by rapid regression of mouth tumors in mice afflicted with Cowden syndrome with the administration of rapamycin. Like HNSCC, development of this disease is linked to over activation of the Akt/mTOR pathway. Furthermore, the therapeutic potential of rapamycin was demonstrated using mice in experiments that model chronic exposure to tobacco, which promotes the development of HNSCC. Therefore, inhibitors of mTOR have considerable potential in the prevention and treatment of HNSCC. Moreover, using a local, sustained-release oral drug delivery system for early intervention to prevent potentially malignant or