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.*

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_L 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: *hastingw@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

premalignant lesions developing into HNSCC, could deliver the inhibitors of mTOR with reduced systemic side effects and a lower required drug dose.

The prospective exclusive license and any further license applications received as objections to this Notice of Intent to Grant an 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 evaluation option license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization 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 fifteen (15) days from the date of this published notice. A previous Notice of Intent to Grant an Exclusive License for the instant technology was published in 77 FR 28614, Tuesday, May 15, 2012.

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 25, 2012.

Richard U. Rodriguez,

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

[FR Doc. 2012–26606 Filed 10–29–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2012–0026]

Notice of Request for Comments on the Scope of Future Revisions to ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants'' (NUREG–0654/FEMA–REP–1, Rev. 1)

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) is soliciting comments from stakeholders and interested members of the public on the scope of future revisions to ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' (NUREG–0654/FEMA–REP–1, Rev. 1). In association with this request for comments, FEMA and the Nuclear Regulatory Commission (NRC) held two public meetings on August 22, 2012 and September 13, 2012.

DATES: Written comments must be submitted to FEMA by January 31, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. FEMA–2012–0026, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail/Hand Delivery/Courier:* FEMA, Regulatory Affairs Division, Office of Chief Counsel, 500 C Street SW., Room 840, Washington, DC 20472–3100.

Instructions: Direct your comments to Docket ID No. FEMA–2012–0026. All submissions received must include the agency name and docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal e-Rulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. Please be aware that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual who submitted the comment (or signed the comment, if submitted on behalf of an association, business, labor union, etc.). You may want to review the Federal Docket Management System of records notice published in the **Federal Register** on March 24, 2005 (70 FR 15086).

Do not submit comments that include trade secrets, confidential commercial or financial information to the public regulatory docket. Comments containing this type of information should be appropriately marked as containing such information and submitted by mail to the address specified in the **ADDRESSES** section of this notice. If FEMA receives a request to examine or copy this information, FEMA will treat it as any other request under the Freedom of Information Act (FOIA), 5 U.S.C. 552, and the Department of Homeland Security (DHS)'s FOIA regulation found in 6 Code of Federal Regulations (CFR) Part 5 and FEMA's regulations found in 44 CFR Part 5.

Docket: For access to the docket to read background documents or comments received, go to the Federal eRulemaking Portal at *http://www.regulations.gov,* click on ''Advanced Search,'' then enter ''FEMA–2012–0026'' in the ''By Docket ID'' box, then select ''FEMA'' under ''By Agency,'' and then click ''Search.'' Submitted comments may also be inspected at FEMA, Office of Chief Counsel, Room 835, 500 C Street SW., Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Vanessa Quinn, Radiological Emergency Preparedness Branch Chief, Radiological Emergency Preparedness Branch, Technological Hazards Division, National Preparedness Directorate, Federal Emergency Management Agency; Phone Number: 703–605–1535.

SUPPLEMENTARY INFORMATION: FEMA, working with the Nuclear Regulatory Commission (NRC), is soliciting comments from stakeholders and interested members of the public on the scope of future revisions to ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' NUREG–0654/FEMA–REP–1, Rev. 1. The document is available online at *http://www.regulations.gov* (Docket ID FEMA–2012–0026).

NUREG–0654/FEMA–REP–1, Rev.1 is a joint FEMA/NRC policy document that provides guidance on the sixteen Planning Standards referenced in FEMA's regulations at 44 CFR 350.5 and the NRC's regulations at 10 CFR part 50. Both agencies use these Planning Standards to evaluate the adequacy of the emergency plans of commercial nuclear power plant owners and operators (NRC), and the emergency plans and preparedness of State and local governments within the Emergency Planning Zones surrounding commercial nuclear power plants (FEMA).

Since the publication of NUREG–0654/FEMA–REP–1, Rev.1 in November 1980, four supplementary documents and one addendum have been issued that update and modify specific planning and procedural elements. These documents are available online at *http://www.regulations.gov* (Docket ID FEMA–2012–0026). FEMA and the NRC are considering revising NUREG–0654/FEMA–REP–1, Rev.1 to address stakeholder interest and the various emergency planning and preparedness lessons learned since its initial publication.

FEMA and the NRC held two public meetings on August 22, 2012 and