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 patent 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” (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.

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 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. Any additional 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: May 9, 2012.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

FOR FURTHER INFORMATION CONTACT: 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.

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.

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 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. Any additional 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: May 9, 2012.

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

SUMMARY: This is notice to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately $130,000 (total costs) for up to one year to the University of California Los Angeles (UCLA). This is not a formal request for applications. Assistance will be provided only to the University of California Los Angeles (UCLA) based on the receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: TI–12–001

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Foreign Operations and Related Programs Appropriations Act, 2010 (Division F, Pub. L. III–J 17). Funding for this program is made available through the State Department.

Justification: Only the University of California Los Angeles (UCLA) is eligible to apply. The Substance Abuse and Mental Health Services Administration (SAMHSA) is seeking to award a supplemental grant to the University of California Los Angeles (UCLA) to expand/enhance grant activities funded under the FY 2011 Cooperative Agreement for the Drug Demand Reduction Initiative for Iraq. This initiative builds on work begun as part of the 2010 Iraq-SAMHSA Initiative, which supported a team of
behavioral health professionals from the Government of Iraq (COI Team) who visited substance abuse sites in the U.S. to learn about establishing substance abuse services and training.

The purpose of the supplemental funding is to provide logistical and fiscal management support, and training for project-related activities in Iraq, including SBIRT and other trainings planned to take place in Iraq. At a minimum the funds awarded will be used to conduct the following activities:

- Develop a plan to provide logistical and fiscal management support for project-related activities in Iraq, including SBIRT and other trainings planned to take place in Iraq.
- Develop a plan for the United Nations Office on Drugs and Crime rapid assessment of the current substance use trends in Iraq and assist in the establishment of the Community Epidemiology Workgroup.
- Provide an implementation plan in the context of the overall project and an updated timeline, which shows how funds will be used to enhance logistics and financial management of the project.
- Provide a plan on how individuals served as a result of the supplemental activities will be incorporated into the ongoing Government Performance and Results Modernization Act of 2010 (GPRA) activities.

Contact: Shelly Hara, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8–1099, Rockville, MD 20857; telephone: (240) 276–2321; Email: shelly.hara@samhsa.hhs.gov.

Cathy Friedman, SAMHSA Public Health Analyst.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately $375,000 (total costs) for up to one year to the Natividad Medical Center in Salinas, CA. This is not a formal request for applications. Assistance will be provided only to the Natividad Medical Center based on the receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: TI–12–009.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section 509 of the Public Health Service Act, as amended.

Justification: Only the Natividad Medical Center in Salinas, CA is eligible to apply. The Substance Abuse and Mental Health Services Administration (SAMHSA) is seeking to award a supplemental grant to the Natividad Medical Center in Salinas, CA, to enable Natividad to continue to develop and implement a training program to teach medical residents skills to provide evidence-based screening, brief intervention, brief treatment and referral to specialty treatment for patients who have, or are at risk for, a substance use disorder as required under the FY 2008 Request for Applications (RFA). This organization was funded under the SBIRT Medical Residency grant program (TI–08–003) in FY 2008. Under the leadership at that time, the Natividad Medical Center received a 4-year grant, although the SBIRT Medical Residency Program is a 5-year program.

Subsequent to the original award, new leadership for the grant program has been put in place. As a result, the new leadership has determined that in order to execute the full requirements of the program and to meet the necessary client targets, the final year of funding is required. The purpose of this sole source award is to fund the last year of the 5-year cooperative agreement awarded under the initial announcement. SAMHSA will not accept an application from any other entity. Natividad Medical Center is in the unique position to be awarded one year funding because:

- Natividad Medical Center to date has successfully implemented the SBIRT Medical Residency Program since 2008, and a fifth year of funding would give the program an additional year to train more residents in SBIRT as well as allow the program to solidify sustaining its training program after the end of SAMHSA funding.
- Natividad Medical Center is the only SBIRT Medical Residency Program grantee in Central California, and serves minority, high-risk and vulnerable populations, including farm workers, low-income individuals, adolescents, elderly, homeless, veterans, and individuals with substance abuse and co-occurring disorders.

Contact: Cathy Friedman, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8–1099, Rockville, MD 20857; telephone: (240) 276–2316; Email: cathy.friedman@samhsa.hhs.gov.

Cathy Friedman, SAMHSA Public Health Analyst.