

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Mesothelin-Expressing Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of 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 listed in the Supplementary Information section of this notice to Evotec International GmbH (Evotec), located in Hamburg, Germany.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before June 16, 2022 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: David A. Lambertson, Ph.D., Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240) 276-6467; Email: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application 62/508,197 entitled "Anti-Mesothelin Polypeptides and Proteins" [HHS Ref. E-106-2017-0-US-01], PCT Patent Application PCT/US2018/033236 entitled "Anti-Mesothelin Polypeptides and Proteins" [HHS Ref. E-106-2017-0-PCT-02], U.S. Patent Application 16/631,971 entitled "Anti-Mesothelin Polypeptides and Proteins" [HHS Ref. E-106-2017-0-US-03], U.S. Provisional Patent Application 63/290,761 entitled "Anti-Mesothelin Polypeptides and Proteins" [HHS Ref. E-033-2021-0-US-01], and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The license to be granted may be worldwide, and may be limited to the following field of use:

"The development, production and commercialization of a mono-, bi-, or multi-specific anti-MLSN (Mesothelin) chimeric antigen receptor (CAR)-based allogeneic immunotherapy using genetically engineered, iPSC-derived human NK cells where the CAR has at least:

- (1) The complementary determining region (CDR) sequences of the (humanized) anti-MLSN antibody known as 15B6;
- (2) A transmembrane domain; and
- (3) At least one signaling domain, for the treatment of MSLN-expressing solid tumors."

Mesothelin is a cell surface protein that is expressed on a number of types of cancer cells, including mesothelioma, pancreatic cancer, ovarian cancer, and certain lung cancers. There are currently few effective therapies for patients with these types of cancers, with many patients experiencing disease relapse. Upon relapse, there are even fewer second-line therapeutic options, underscoring an unmet patient need. The development of an anti-mesothelin CAR-based therapy can potentially be used for the treatment of mesothelin-expressing cancers. As a result, the development of a new therapeutic option targeting mesothelin will benefit public health by providing an effective treatment for patients that might otherwise have no options.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute 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.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 25, 2022.

Richard U. Rodriguez,
Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2022-11666 Filed 5-31-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Substance Abuse and Mental Health Services Administration has modified its structure. This new organizational structure was approved by the Deputy Secretary of Health and Human Services on April 27, 2022 and became effective on May 13, 2022.

FOR FURTHER INFORMATION CONTACT: Robert T. Atanda, Ph.D., Director, Division of Management Services, Office of Management, Technology, and Operations, Substance Abuse and Mental Health Services Administration, Parklawn Building, Room 12E49, 5600 Fishers Lane, Rockville, MD, 20857
Phone: 240-276-2826

Part M of the Substance Abuse and Mental Health Services Administration (SAMHSA) Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (DHHS) at 73, Number 147, pages 44274-44275, July 30, 2008, is amended to reflect the new functional statement for the Center for Substance Abuse Prevention. This notice identifies a new Office of Prevention Innovation (OPI). This change allows innovative prevention implementation. The changes are as follows:

Section M.20, Functions is amended as follows:

The functional statement for the Center for Substance Abuse Prevention is amended to name a new Office of Prevention Innovation. The functional statement for each office is as follows:

Office of Prevention Innovation

The Office of Prevention Innovation (OPI) will provide support across the Center to promote leading edge programming in the substance misuse prevention and mental health promotion fields. The focus of the OPI team is to drive innovative prevention programming by analyzing program data to uncover common barriers to program implementation, as well as innovative approaches, and quickly turn these into technical assistance to the field. Historically, program evaluations have focused on long-term, big picture evaluation questions. OPI seeks to use a quick-turnaround implementation science and technical assistance model

to improve programs over the lifetime of the grant.

The substance misuse landscape in the country is rapidly changing. Substance misuse patterns are changing constantly, as has been seen during the pandemic. New, high-risk substances are emerging, such as synthetic drugs like Fentanyl, psilocybin, new and more potent strains of cannabis. Substance availability policies and practices are rapidly evolving, such as home delivery of alcohol, cannabis legalization, and fake drugs being sold on social media platforms. In addition, the stresses and strains on the Nation's population, including health and climate-related emergencies and disasters and related economic and social upheavals. Together, these factors demand that CSAP modernize its approach to supporting the substance use prevention field, in a way that is data-driven, and more oriented toward rapid-response support to the States, Tribes and communities implementing substance misuse prevention and health promotion activities in the country. The OPI team gives CSAP and SAMSHA the ability to lead this effort.

To accomplish this, the OPI team will work closely with CSAP's two divisions which provide oversight to a portfolio of nearly 1000 State, Tribal and community public health grants, to conduct year-round program analysis, and oversee flexible, rapid-response technical assistance mechanisms to address challenges as they arise, and amplify emerging innovations and best practices.

Office of the Director (MP1)

(1) Provides leadership, coordination, and direction in the development and implementation of CSAP goals and priorities, and serves as the focal point for the Department's efforts on substance abuse and HIV/AIDS prevention; (2) plans, directs, and provides overall administration of the programs and activities of CSAP; (3) provides leadership in the identification of new and emerging issues, and the integration of primary prevention, early intervention, re-entry and relapse prevention, knowledge and information in the major CSAP programs; (4) manages special projects and external liaison activities; and (5) directs CSAP's overall human resource activities and monitors the conduct of equal employment opportunity activities for CSAP.

Office of Program Analysis and Coordination (MPA)

(1) Supports the Center's implementation of programs and

policies by providing guidance in the administration, analysis, planning, and coordination of the Center's programs, consistent with agency priorities; (2) manages the Center's participation in the agency's policy, planning, budget formulation and execution, program development and clearance, and internal and external requests, including strategic planning, identification of program priorities, development of Healthy People 2010, and other agency-wide and departmental planning activities; (3) provides support for the Center Director; coordinates staff development activities, analyzes the impact of proposed legislation and rule-making; supports administrative functions, including human resource actions; conducts special studies; serves as liaison for special populations/initiatives including White House Executive Orders for specific minority populations; (4) manages CSAP's National Advisory Council activities; and (5) coordinates CSAP's evaluation program.

Division of Primary Prevention (MPJ)

The Division of Primary Prevention is responsible for carrying out the Center's agenda to increase capacity and improve accessibility of effective substance abuse prevention across States, American Indian/Alaska Native Tribes, and tribal organizations. The Division provides most program services through two regional teams. The Division (1) plans, develops and administers programs to implement comprehensive and effective State substance abuse prevention systems and other related health promotion systems; (2) promotes and establishes comprehensive, long-term State and tribal substance abuse prevention/intervention policies, programs, practices, and support activities to address substance abuse and related emerging issues; (3) administers the prevention set-aside of the Substance Abuse Prevention and Treatment (SAPT) Block Grant; (4) collaborates with other units in the application of SAMHSA's Strategic Prevention Framework with States and Tribes; (5) develops funding announcements, ensures coordination with grant management systems, and administers national discretionary grant programs, such as the Strategic Prevention Framework State Incentive grant (SPF SIG) program; (6) administers the Synar regulations governing youth access to tobacco products; (7) works across CSAP and SAMHSA to promote inter/intra-agency collaboration at the Federal, State and tribal levels; serves as the liaison for CSAP interactions with State agency and National Prevention

Network officials on State issues; monitors State progress in achieving National Outcome Measures and plans for associated technical assistance; monitors compliance with Block Grant and other Federal requirements.

Division of Targeted Prevention (MPH)

The Division of Targeted Prevention is responsible for carrying out the Center's agenda to increase capacity and improve accessibility of effective substance abuse prevention services across communities. This includes management of all CSAP grants targeted to communities and non-profit organizations, such as Drug Free Communities, HIV/AIDS, methamphetamine, and conference grants. The Division is organized into three branches with responsibility to (1) plan, develop, and administer programs of regional and national significance to enhance comprehensive and effective community substance abuse prevention systems, including disaster relief programs; (2) promote and establish comprehensive substance abuse prevention/intervention policies, programs, practices, and support services to address substance abuse and emerging issues; (3) collaborate with other units in the application of SAMHSA's Strategic Prevention Framework in community prevention systems; (4) develop funding announcements, ensure coordination with grant management systems, and administer discretionary grant programs; (5) work across SAMHSA to promote interagency collaboration; (6) monitor grantee and contractor progress in achieving National Outcome Measures, and plan associated technical assistance; and (7) monitor compliance with all Federal requirements.

Division of Prevention Communications and Public Engagement (MPI)

The Division of Prevention Communications and Public Engagement provides leadership and guidance in the planning, development, and implementation of programs and prevention concepts across the Center and is responsible for carrying out the Center's health promotion and public education activities. The Division's responsibilities include (1) promotion and implementation of key prevention concepts across all programs and activities of the Center, including the Strategic Prevention Framework, project sustainability, and coordination/integration of community and State programs; (2) management of technical assistance contracts that support all of the Center's prevention programs; (3) coordination of CSAP's GPRA and

National Outcome Measure activities, including liaison with offices responsible for data collection; (4) analysis of data related to program operations and assistance to other CSAP components in employing data to improve program performance; (5) analysis, development, and integration of information, including evidence-based practices and NREPP programs, necessary to improve State and community prevention service delivery; (6) leadership within SAMHSA in the development, training and use of geographic information system (GIS) resources to improve policy development and program operations; (7) collaboration with Federal, State, and local governments to promote the adoption of evidence-based prevention programs and practices and develop innovative strategies to address emerging substance abuse issues; (8) initiation, development, and coordination of efforts to support workforce development for substance abuse prevention professionals; (9) leadership to the Center in the development of health promotion and education products, materials, messages, publications, and information technologies; (10) collaboration with other Federal and private sector prevention initiatives in developing and disseminating targeted prevention material, including the SAMHSA Office of Communications; (11) development and continual update of prevention material for use by external prevention partners.

Division of Workplace Programs (MPE)

(1) Establishes goals and objectives in the administration of a national program designed to promote substance abuse free workplaces; (2) provides leadership and oversight to assure that effective employee assistance programs are developed and evaluated to prevent substance abuse in the workplace; (3) develops, implements, and evaluates employee education/prevention programs, access to counseling, early intervention, and referral treatment/rehabilitation, and support services for employees following treatment/rehabilitation; (4) advises, coordinates, and certifies activities related to the implementation and administration of federal drug free workplace programs, convenes the Drug Testing Advisory Board, and conducts surveys on federal programs; (5) advises other SAMHSA components and HHS regarding workplace programmatic directions and actions and enters into collaborative arrangements with other federal agencies; (6) collaborates in the development and implementation of

substance abuse prevention and early intervention strategies for public/private sector use at the State and community levels, and operates the Workplace Hotline Contract as a means for dissemination, outreach and technical assistance to businesses, States and communities; (7) provides technical assistance to facilitate national training and certification programs for substance abuse professionals and practitioners, provides staff expertise in training and credentialing standards for medical review officers (MROs) and the Department of Transportation mandated substance abuse professionals; (8) provides leadership within SAMHSA and the field in developing and disseminating knowledge in workplace violence related to substance abuse, including risk factors in the workplace and community and the role of the workplace as a substance abuse and violence prevention agent within the community and family; and (9) evaluates managed care and other treatment provider practices as they are applied in the workplace.

Delegation of Authority

All delegations and re-delegations of authority to officers and employees of SAMHSA which were in effect immediately prior to the effective date of this reorganization shall continue to be in effect pending further re-delegations, provided they are consistent with this reorganization.

This delegation of authority is effective immediately.

Dated: May 26, 2022.

Xavier Becerra,

Secretary, U.S. Department of Health and Human Services.

[FR Doc. 2022-11748 Filed 5-31-22; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection [1651-0121]

Trusted Traveler Programs and U.S. APEC Business Travel Card

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-day notice and request for comments; revision of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request

to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than August 1, 2022) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651-0121 in the subject line and the agency name. Please use the following method to submit comments:

Email. Submit comments to: CBP_PRA@cbp.dhs.gov.

Due to COVID-19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

FOR FURTHER INFORMATION CONTACT:

Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229-1177, Telephone number 202-325-0056 or via email CBP_PRA@cbp.dhs.gov. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877-227-5511, (TTY) 1-800-877-8339, or CBP website at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to