

Intellectual Property

United States Provisional Patent Application No. 61/040,005, filed March 27, 2008 and entitled "Human Monoclonal Antibodies Specific for Mesothelin" [HHS Reference No. E-079-2008/0-US-01];

PCT Patent Application PCT/US2009/038228, filed March 25, 2009 and entitled "Human Monoclonal Antibody Against Mesothelin" [HHS Reference No. E-079-2008/0-PCT-02]; and US Patent No. 8,357,783, filed September 22, 2010, Issued January 22, 2013 and entitled "Human Anti-Mesothelin Monoclonal Antibodies" [HHS Reference No. E-079-2008/0-US-06].

The patent rights in these inventions have been assigned 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 development of a mesothelin chimeric antigen receptor (CAR)-based immunotherapy using autologous or allogeneic T cells either transduced with a retroviral vector (including lentiviral vectors) or modified using a gene-editing technology, wherein the vector expresses a CAR comprising:

(1) Single antigen specificity for binding to mesothelin, and

(2) at least (a) the complementary determining region (CDR) sequences of the anti-mesothelin antibody known as m912, and (b) a T cell signaling domain; for the prophylaxis and treatment of mesothelin-expressing human cancers."

This technology discloses a monoclonal antibody and methods of using the antibody for the treatment of mesothelin-expressing cancers, including mesothelioma, lung cancer, stomach/gastric cancer, ovarian cancer, and pancreatic cancer. The specific antibody covered by this technology is designated as m912, which is a fully human monoclonal antibody against mesothelin.

Mesothelin is a cell surface antigen that is preferentially expressed on certain types of cancer. The m912 antibody selectively binds to the mesothelin on the surface of cancer cells and induces cell death of those cancer cells while leaving healthy cells unharmed. This selectivity may lead to fewer side effects due to decreased non-specific killing of cells.

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: June 21, 2018

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2018-13893 Filed 6-27-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Office of the Secretary; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the Interagency Pain Research Coordinating Committee, July 09, 2018, 02:00 p.m. to July 09, 2018, 04:00 p.m., National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD, 20892 which was published in the **Federal Register** on May 18, 2018, 83 FR 23283.

The meeting notice is amended to change the time of the meeting from 2-4 p.m. to 4-6 p.m. Date has not changed. The meeting is open to the public.

Dated: June 22, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-13895 Filed 6-27-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Substance Abuse and Mental Health Services Administration****Notice of Meetings**

AGENCY: Substance Abuse and Mental Health Services Administration; Centers

for Disease Control and Prevention; Department of Health and Human Services.

ACTION: Notice of meetings.

SUMMARY: Notice is hereby given of the meetings on July 22-23, 2018, of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Tribal Technical Advisory Committee (TTAC); on July 23 and July 25, 2018, of the Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR) Tribal Advisory Committee (TAC); and on July 24, 2018, of the Joint Tribal Advisory Committee (JTAC).

DATES:

SAMHSA TTAC

July 22, 2018, 1:00 p.m. to 5:00 p.m. EDT (OPEN)

July 23, 2018, 9:00 a.m. to 5:00 p.m. EDT (OPEN)

• CDC/ATSDR TAC

July 23, 2018, 8:00 a.m. to 6:00 p.m. EDT (OPEN)

July 25, 2018, 8:00 a.m. to 12:00 p.m. EDT (OPEN)

• JTAC

July 24, 2018, 1:00 p.m. to 5:00 p.m. EDT, (OPEN)

ADDRESSES:

• SAMHSA TTAC

Marriott Wardman Park Hotel, 2660 Woodley Road NW, Washington, DC 20008

• CDC/ATSDR TAC

HHS Headquarters, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201

• JTAC

HHS Headquarters, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT:

TTAC and JTAC, Mirtha Beadle, MPA, Director, Office of Tribal Affairs and Policy, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (240) 276-0641, Email: otap@samhsa.hhs.gov.

CDC/ATSDR/TAC, Carmen Clelland, PharmD, MPA, MPH, Associate Director for Tribal Support, Office for State, Tribal, Local and Territorial Support, Centers for Disease Control and Prevention, 4770 Buford Highway, Mailstop E-70, Atlanta, GA 30341-3717, Telephone: (404) 498-2205, Email: ccllelland@cdc.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Presidential Executive Order 13175 signed on November 6, 2000 and the Presidential Memorandum of September 23, 2004, SAMHSA established the

TTAC to provide a complementary venue wherein tribal leaders and SAMHSA officials exchange information about public health issues in Indian Country; identify urgent mental health and substance abuse needs in tribal communities; and discuss collaborative approaches for addressing issues and needs. The SAMHSA TTAC serves as a national advisory body to SAMHSA.

The TTAC meeting will include updates and discussion related to tribal priorities for SAMHSA; collaborative opportunities between SAMHSA and CDC/ATSDR; behavioral health policy, budget, and legislative activities; tribal input in response to recent consultation and listening sessions; and essential coordination with other SAMHSA and HHS efforts to improve tribal behavioral health and wellness.

The purpose of the CDC/ATSDR TAC meeting is to advance CDC and ATSDR support for and partnership with American Indian and Alaska Native (AI/AN) tribes, and to improve the health of tribes by pursuing goals that include assisting in eliminating the health disparities faced by tribes; ensuring that access to critical health and human services is maximized to advance or enhance the social, physical, and economic status of AI/AN people; and promoting health equity for all AI/AN people.

The CDC/ATSDR TAC agenda will include discussions on tribal priorities for CDC and ATSDR, public health capacity in Indian Country, AI/AN health concerns, CDC and ATSDR budget and funding opportunities, and programmatic highlights from the agencies. Agenda items are subject to change as priorities dictate. All tribal leaders are encouraged to submit written testimony for the CDC/ATSDR TAC by 5:00 p.m. EDT Friday, July 15, 2018, to Captain Carmen Clelland, Associate Director of Tribal Support, OSTLTS, via mail to 4770 Buford Highway NE, MS E-70, Atlanta, GA, 30341-3717, or email TribalSupport@cdc.gov. Tribal leaders can find guidance to assist in developing tribal testimony for CDC and ATSDR at www.cdc.gov/tribal/consultation.

The TTAC and JTAC meetings are open to the public. Interested persons may submit data, information, or views on issues pending before the TTAC or JTAC in writing. The designated SAMHSA contact official must receive TTAC and JTAC submissions no later than July 15, 2018. Individuals interested in making public comments during the TTAC meeting must notify the designated SAMHSA contact official by July 15, 2018. Time is available for

public comments at the end of the TTAC meeting on July 23 (two minutes will be allotted for each public comment). Oral comments will not be scheduled for the JTAC meeting.

The TTAC and JTAC meetings are accessible via web conferencing. To attend on site, obtain web conferencing information, submit written comments, provide brief oral comments (TTAC only), or request special accommodations for persons with disabilities, please register online at: <http://nac.samhsa.gov/Registration/meetingsRegistration.aspx>, or submit information for Mirtha Beadle, Director, Office of Tribal Affairs and Policy, SAMHSA, at otap@samhsa.hhs.gov.

SAMHSA and CDC are publishing their committee meeting notices together as CDC/ATSDR TAC members will join the SAMHSA TTAC for a collaborative discussion on July 22. Further, based on recommendations from tribal leaders, a JTAC meeting has been scheduled to discuss issues of common concern across the SAMHSA TTAC, CDC/ATSDR TAC, Indian Health Service (IHS) National Tribal Advisory Committee on Behavioral Health, and other U.S. Department of Health and Human Services (HHS) operating division tribal advisory committees. The intent of the JTAC meeting is to improve coordination across shared TAC topics to strengthen tribal health. The topics for JTAC discussion include improving data on American Indian and Alaska Native Health and the tribal health workforce (*i.e.*, primary care, behavioral health, public health, research, etc.).

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2018-13878 Filed 6-27-18; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2018-0002; Internal Agency Docket No. FEMA-B-1832]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA)

boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before September 26, 2018.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location <https://www.fema.gov/preliminaryfloodhazarddata> and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

You may submit comments, identified by Docket No. FEMA-B-1832, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).