

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Autologous Tumor Infiltrating Lymphocyte Adoptive Cells for the Treatment of Metastatic Melanoma

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to the current licensee, Lion Biotechnologies, Inc., which is located in Woodland Hills, California to practice the inventions embodied in the following patent applications and applications claiming priority to these applications:

1. U.S. Provisional Patent Application No. 61/237,889, filed August 26, 2009 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-01);

2. U.S. Patent No. 8,383,099 issued February 26, 2013 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-02);

3. U.S. Patent Application No. 13/742,541 filed January 16, 2013 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-03);

4. U.S. Provisional Patent Application No. 61/466,200 filed March 22, 2011 entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-US-01);

5. PCT Application No. PCT/US2012/029744 filed March 20, 2012 entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-US-01);

6. U.S. Patent Application No. 13/424,646 filed May 20, 2012 entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-US-01);

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights to develop, manufacture, distribute, sell and use autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of metastatic melanoma as a stand-alone therapy.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before December 24, 2014 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., Senior 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: Isolating cells from the tumor infiltrating lymphocytes (TIL) of a patient tumor sample provides a suitable initial lymphocyte culture for further in vitro manipulations. NIH scientists have discovered that taking the isolated cells through one cycle of rapid expansion (including exposure to IL-2), rather than multiple cycles, yields lymphocyte cultures with higher affinity and longer persistence in patients. In addition, they have found that through the use of gas permeable (GP) flasks, they could obtain large quantities of highly reactive TIL from patient tumor samples for anti-cancer immunotherapy. If an adoptive T cell transfer immunotherapy is to gain regulatory approval and successfully treat a wide array of patients, it will need to be rapid, reliable, and technically simple. One of the most critical factors to this approach is the generation of effective lymphocyte cultures that will rapidly and repeatedly attack the target cells when infused into patients.

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 part 404.

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 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: November 17, 2014.

Richard U. Rodriguez,
Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014-27680 Filed 11-21-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel Production, Analysis, and Distribution of Cannabis and Related Materials (7793).

Date: December 2, 2014.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lyle Furr, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892-9550, (301) 435-1439, lf33c.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.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 18, 2014.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-27669 Filed 11-21-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the

National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Heart, Lung, and Blood Advisory Council.

Date: February 10, 2015.

Open: 8:00 a.m. to 1:00 p.m.

Agenda: To discuss program policies and issues, including the NHLBI Advisory Council Asthma Expert Working Group's report on Asthma Guidelines Needs Assessment. The Working Group's draft report can be found at <http://www.nhlbi.nih.gov/health/resources/lung/nhlbiac-asthma-report.htm> and comments may be submitted to Asthma_Needs_Assessment_Comments@nhlbi.nih.gov by January 5, 2015.

Place: National Institutes of Health, Building 31, 6th Floor, C Wing, 31 Center Drive, Bethesda, MD 20892.

Closed: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 6th Floor, C Wing, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Stephen C. Mockrin, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7100, Bethesda, MD 20892, (301) 435-0260, mockrins@nhlbi.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page:

www.nhlbi.nih.gov/meetings/nhlbiac/index.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 18, 2014.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-27671 Filed 11-21-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the NIH Scientific Management Review Board (SMRB). On December 15, 2014, the SMRB will deliberate findings and recommendations developed by the SMRB Working Group on Pre-college Engagement in Biomedical Science. The Working Group has considered approaches to optimize NIH's pre-college programs and initiatives that both align with the NIH mission and ensure a continued pipeline of biomedical science students and professionals. SMRB members will also discuss preliminary findings and recommendations for streamlining NIH's grant review, award, and management process while maintaining proper oversight. Panel discussions will be held with grantees and other stakeholders.

The NIH Reform Act of 2006 (Pub. L. 109-482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the SMRB is to advise appropriate HHS and NIH officials on the use of these organizational authorities and

identify the reasons underlying the recommendations.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. Times are subject to change.

Name of Committee: Scientific Management Review Board (SMRB).

Date: December 15, 2014.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: At this meeting, SMRB members will deliberate findings and recommendations developed by the Working Group on Pre-college Engagement in Biomedical Science. The Working Group on the NIH Grant Review, Award, and Management Process will report their preliminary findings and recommendations on ways to streamline the process, and grantees and other stakeholders will share insights regarding the effectiveness and feasibility of the recommendations. Time will be allotted on the agenda for public comment. Sign up for public comments will begin approximately at 8:00 a.m. on December 15, 2014, and will be restricted to one sign-in per person. In the event that time does not allow for all those interested to present oral comments, any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Juanita Marner, Office of Science Policy, Office of the Director, NIH, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, smrb@mail.nih.gov, (301) 435-1770.

The meeting will also be webcast. The draft meeting agenda and other information about the SMRB, including information about access to the webcast, will be available at <http://smrb.od.nih.gov>.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate