

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Modulation of Iron Deposition in SCD and Other Hemoglobinopathies.

Date: July 9, 2008.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7799, ls38oz@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 11, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-13701 Filed 6-17-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Geldanamycin Derivative and Method of Treating Viral Infections

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 Part 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 invention embodied in U.S. Patent No. 6,890,917, issued May 10, 2005, entitled "Geldanamycin Derivative and Method of Treating Cancer Using Same" [E-050-2000/0-US-15] and foreign equivalents, to Avira Therapeutics, LLC, having a place of business in Menlo Park, California. 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 manufacture, use, distribution and sale of 17-DMAG, an analog of geldanamycin, as a therapeutic to inhibit the influenza virus, respiratory syncytial virus (RSV) and dengue virus.

This replaces a notice published in 73 FR 31702 on Tuesday, June 3, 2008, which omitted the name of the potential licensee.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before August 18, 2008 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: Adaku Madu, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5560; Facsimile: (301) 402-0220; E-mail: madua@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This technology relates to novel cytotoxic compounds derived from 17-aminoalkylamino-substituted geldanamycin and pharmaceutical compositions thereof. In particular, this invention refers to 17-(dimehtylamino) propylamino-geldanamycin, 17-(dimethylamino) ethylamino-geldanamycin, and the hydrochloride salt of 17-(dimethylamino) ethylamino-geldanamycin (DMAG and analogs). These compounds are Hsp90 inhibitors. Hsp90 inhibition downregulates B-Raf, decreases cell proliferation and reduces activation of the MEK/ERK pathways in some cells. Hsp90 plays an essential role in maintaining stability and activity in its client proteins. Hsp90 inhibitors interfere with diverse signaling

pathways by destabilizing and attenuating activity of such proteins, and thus exhibit antitumor activity. Specifically, 17-DMAG shows cytotoxicity against a number of human colon and lung cell lines, specific melanoma, renal and breast lines, and potentially against various viral infections. In addition, these compounds appear to have favorable pharmaceutical properties including oral activity and improved water-solubility.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within sixty (60) 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.

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: June 9, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8-13671 Filed 6-17-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

DEPARTMENT OF STATE

Office of the Secretary

Exercise of Authority Under Section 212(d)(3)(B)(i) of the Immigration and Nationality Act

AGENCY: Office of the Secretary, DHS; Office of the Secretary, DOS.

ACTION: Notice of Determination.

DATES: This determination is effective June 3, 2008.

Authority: 8 U.S.C. 1182(d)(3)(B)(i).

The Secretary of Homeland Security and the Secretary of State, following consultations with the Attorney General, hereby conclude, as a matter of

discretion in accordance with our respective authorities under section 212(d)(3)(B)(i) of the Immigration and Nationality Act (INA), 8 U.S.C. 1182(d)(3)(B)(i), as amended by the Consolidated Appropriations Act, 2008 (CAA), Public Law 110-161, Div. J, section 691(a), 121 Stat. 1844, 2364 (December 26, 2007), as well as the foreign policy and national security interests deemed relevant in these consultations, that section 212(a)(3)(B) of the INA, excluding subclause (i)(II), shall not apply with respect to an alien not otherwise covered by the automatic relief provisions of section 691(b) of the CAA, for any activity or association relating to appropriate groups affiliated with the Montagnards, provided that there is no reason to believe that the relevant terrorist activities of the alien or the recipients were targeted against noncombatant persons, and further provided that the alien satisfies the relevant agency authority that the alien:

(a) Is seeking a benefit or protection under the INA and has been determined to be otherwise eligible for the benefit or protection;

(b) Has undergone and passed relevant background and security checks;

(c) Has fully disclosed, in all relevant applications and interviews with U.S. government representatives and agents, the nature and circumstances of each activity or association falling within the scope of section 212(a)(3)(B) of the INA;

(d) Poses no danger to the safety and security of the United States; and

(e) Is warranted to be exempted from the relevant inadmissibility provision by the totality of the circumstances.

Implementation of this determination will be made by U.S. Citizenship and Immigration Services (USCIS), in consultation with U.S. Immigration and Customs Enforcement (ICE), or by U.S. consular officers, as applicable, who shall ascertain, to their satisfaction, and in their discretion, that the particular applicant meets the criteria set forth above.

This exercise of authority may be revoked as a matter of discretion and without notice at any time with respect to any and all persons subject to it. Any determination made under this exercise of authority as set out above shall apply to any subsequent benefit or protection application, unless such exercise of authority has been revoked.

This exercise of authority shall not be construed to prejudice, in any way, the ability of the U.S. government to commence subsequent criminal or civil proceedings in accordance with U.S. law involving any beneficiary of this exercise of authority (or any other person). This exercise of authority is not

intended to create any substantive or procedural right or benefit that is legally enforceable by any party against the United States or its agencies or officers or any other person.

In accordance with section 212(d)(3)(B)(ii) of the INA, 8 U.S.C. 1182(d)(3)(B)(ii), a report on the aliens to whom this exercise of authority is applied, on the basis of case-by-case decisions by the Department of Homeland Security or by the Department of State, shall be provided to the specified congressional committees not later than 90 days after the end of the fiscal year.

This determination is based on an assessment related to the national security and foreign policy interests of the United States as they apply to the particular persons described herein and shall not have any application with respect to other persons or to other provisions of U.S. law.

Dated: June 3, 2008.

Michael Chertoff,
Secretary of Homeland Security.

Condoleezza Rice,
Secretary of State.

[FR Doc. E8-13638 Filed 6-17-08; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

DEPARTMENT OF STATE

Office of the Secretary

Exercise of Authority Under Section 212(d)(3)(B)(i) of the Immigration and Nationality Act

AGENCY: Office of the Secretary, DHS; Office of the Secretary, DOS.

ACTION: Notice of determination.

DATES: This determination is effective June 3, 2008.

Authority: 8 U.S.C. 1182(d)(3)(B)(i).

The Secretary of Homeland Security and the Secretary of State, following consultations with the Attorney General, hereby conclude, as a matter of discretion in accordance with our respective authorities under section 212(d)(3)(B)(i) of the Immigration and Nationality Act (INA), 8 U.S.C. 1182(d)(3)(B)(i), as amended by the Consolidated Appropriations Act, 2008 (CAA), Public Law 110-161, Div. J, section 691(a), 121 Stat. 1844, 2364 (December 26, 2007), as well as the foreign policy and national security interests deemed relevant in these consultations, that section 212(a)(3)(B)

of the INA, excluding subclause (i)(II), shall not apply with respect to an alien not otherwise covered by the automatic relief provisions of section 691(b) of the CAA, for any activity or association relating to the Karen National Union/ Karen National Liberation Army (KNU/ KNLA), provided that there is no reason to believe that the relevant terrorist activities of the alien or the recipients were targeted against noncombatant persons, and further provided that the alien satisfies the relevant agency authority that the alien:

(a) Is seeking a benefit or protection under the INA and has been determined to be otherwise eligible for the benefit or protection;

(b) Has undergone and passed relevant background and security checks;

(c) Has fully disclosed, in all relevant applications and interviews with U.S. government representatives and agents, the nature and circumstances of each activity or association falling within the scope of section 212(a)(3)(B) of the INA;

(d) Poses no danger to the safety and security of the United States; and

(e) Is warranted to be exempted from the relevant inadmissibility provision by the totality of the circumstances.

Implementation of this determination will be made by U.S. Citizenship and Immigration Services (USCIS), in consultation with U.S. Immigration and Customs Enforcement (ICE), or by U.S. consular officers, as applicable, who shall ascertain, to their satisfaction, and in their discretion, that the particular applicant meets the criteria set forth above.

This exercise of authority may be revoked as a matter of discretion and without notice at any time with respect to any and all persons subject to it. Any determination made under this exercise of authority as set out above shall apply to any subsequent benefit or protection application, unless such exercise of authority has been revoked.

This exercise of authority shall not be construed to prejudice, in any way, the ability of the U.S. government to commence subsequent criminal or civil proceedings in accordance with U.S. law involving any beneficiary of this exercise of authority (or any other person). This exercise of authority is not intended to create any substantive or procedural right or benefit that is legally enforceable by any party against the United States or its agencies or officers or any other person.

In accordance with section 212(d)(3)(B)(ii) of the INA, 8 U.S.C. 1182(d)(3)(B)(ii), a report on the aliens to whom this exercise of authority is