

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Contact Person: Arnold Revzin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7824, Bethesda, MD 20892, (301) 435-1153, revzina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Stress and Neuroendocrine Responses.

Date: March 29, 2005.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mariela Shirley, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, (301) 435-0913, shirleym@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Bacterial Pathogenesis.

Date: March 29, 2005.

Time: 2:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Marian Wachtel, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3208, MSC 7858, Bethesda, MD 20892, (301) 435-1148, wachtelm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Non-Human Visual Processing.

Date: March 29, 2005.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Christine L. Melchior, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, (301) 435-1713, melchioc@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS.)

Dated: March 1, 2005.

**LaVerne Y. Stringfield,**

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-4500 Filed 3-7-05; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of an Exclusive License: Novel Isosteric Thalidomide Analogs With Enhanced TNF- $\alpha$ Inhibitory Activity

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

**SUMMARY:** This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), announces that the Department of Health and Human Services is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Patent Application No. 60/504,724 filed September 17, 2003, entitled "Thalidomide Analogs" (DHHS Reference E-189-2003/0-US-01) and PCT Application No. PCT/US2004/030506 filed September 17, 2004, entitled "Thalidomide Analogs" (DHHS Ref. E-189-2003/0-PCT-02) to Phase 2 Discovery, Inc. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be United States, Denmark, Italy, Ireland, United Kingdom, Germany, France, Sweden, Switzerland, Spain, Czech Republic, Greece, Russia, Australia, Japan, Taiwan, Singapore, China, Argentina and Brazil, and the field of use may be limited to development and sale of a pharmaceutical product useful in treating Amyotrophic Lateral Sclerosis (ALS) and Attention Deficit Hyperactivity Disorder (ADHD).

**DATES:** Only written comments and/or license applications which are received by the National Institutes of Health on or before May 9, 2005 will be considered.

**ADDRESSES:** Requests for copies of the patent and/or patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Mojdeh Bahar, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804. Telephone: (301) 435-2950; Facsimile: (301) 402-0220; E-mail: baharm@od.nih.gov.

#### SUPPLEMENTARY INFORMATION:

Inflammatory processes associated with the over-production of cytokines, particularly of tumor necrosis factor-alpha (TNF- $\alpha$ ), accompany numerous neurodegenerative diseases, such as Alzheimer's disease and ALS, in

addition to numerous common systemic conditions, such as rheumatoid arthritis, septic shock, graft-versus-host disease, Crohn's disease and erythema nodosum leprosum (ENL). TNF- $\alpha$  has been validated as a drug target with the development of the inhibitors Enbril and Remicade as prescription medications for rheumatoid arthritis. Both, however, are large macromolecules that are expensive to produce, require direct intravenous or subcutaneous injection, and have negligible brain access. The classical orally active drug, thalidomide (N- $\alpha$ -phthalimidoglutaramide), a glutamic acid derivative, is being increasingly used in the clinical management of a wide spectrum of immunologically-mediated, infectious diseases, and cancers. Its clinical value in treating ENL derives from its TNF- $\alpha$  inhibitory activity. Specifically, it inhibits TNF- $\alpha$  protein expression at the post-transcriptional level by facilitating turnover of the mRNA. More recent research has shown similar inhibitory action of COX2 protein expression. These actions are mediated post-transcriptionally via AU-rich elements found in the 3' untranslated regions (3'-UTRs) of each mRNA. Thalidomide's anti-angiogenesis activity derives from its inhibitory actions on basic fibroblast growth factor (bFGF) and vascular endothelial growth factor (VEGF). The agent, additionally, acts as an inhibitor of the transcription factor, NFkB and a co-stimulator of both CD8+ and CD4+ T cells. However, the action of thalidomide to lower TNF- $\alpha$  levels and inhibit angiogenesis is not particularly potent, and it therefore represents an interesting lead compound for medicinal chemistry.

Novel structural modification of thalidomide led to the discovery of original and potent isosteric analogues. The present invention relates to thalidomide analogues and, in particular, thiothalidomides (sulfur-containing thalidomide analogues), methods of synthesizing the analogues, and methods for using the analogues to modulate TNF- $\alpha$  and angiogenesis activities in a subject. Disclosed analogues potently inhibited TNF- $\alpha$  secretion, compared to thalidomide, via post-transcriptional mechanisms that decreased TNF- $\alpha$  mRNA stability via its 3'-UTR. Actions to inhibit angiogenesis were determined in widely accepted *ex vivo* assays.

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 establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 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: February 28, 2005.

**Steven M. Ferguson,**

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

[FR Doc. 05-4488 Filed 3-7-05; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Border and Transportation Security Directorate; Notice of 30-Day Information Collection Under Review for United States Visitor and Immigrant Status Indicator Technology Program (US-VISIT)

**AGENCY:** Border and Transportation Security Directorate, DHS.

**ACTION:** Notice; 30-day notice of information collection under review.

**SUMMARY:** The Department of Homeland Security, Border and Transportation Security Directorate, DHS has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on January 5, 2004, at 69 FR 479, allowing for a 60-day public comment period. No comments were received by DHS on this information collection. The purpose of this notice is to allow an additional 30 days for public comments.

**DATES:** Comments are encouraged and will be accepted until April 7, 2005. This process is conducted in accordance with 5 CFR 1320.10.

**ADDRESSES:** You may submit comments, identified by DHS-2005-0013 by one of the following methods:

- EPA Federal Partner EDOCKET Web site: <http://www.epa.gov/feddoCKET>. Follow instructions for submitting comments on the Web site.

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- E-mail: [Claire.miller@dhs.gov](mailto:Claire.miller@dhs.gov). Include DHS-2005-0013 in the subject line of the message.

- Fax: (202) 298-5060.

- Mail: Office of Management and Budget, Attn: Desk Officer for Homeland Security, Room 10235, Washington, DC 20503.

- Hand Delivery/Courier: Office of Management and Budget, Attn: Desk Officer for Homeland Security, Room 10235, Washington, DC 20503.

**Instructions:** All submissions received must include the agency name and DHS-2005-0013 for this rulemaking. All comments received will be posted without change to <http://www.epa.gov/feddoCKET>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.epa.gov/feddoCKET>. You may also access the Federal eRulemaking Portal at <http://www.regulations.gov>.

#### **SUPPLEMENTARY INFORMATION:**

#### **Request for Comments**

The Office of Management and Budget is particularly interested in comments which:

- Evaluate 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;

- Evaluate 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;

- Enhance the quality, utility, and clarity of the information to be collected; and

- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

#### **Analysis**

**Agency:** Department of Homeland Security, Border and Transportation Security Directorate, DHS.

**Title:** United States Visitor and Immigrant Status Indicator Technology Program (US-VISIT).

**OMB No.:** 1600-0006.

**Frequency:** On occasion.

**Affected Public:** Individual aliens. Non-immigrant visa holders who seek admission to the United States at air and sea ports of entry and designated departure locations.

**Estimated Number of Respondents:** From January 5, 2004, to January 5, 2005, the number of nonimmigrant visa-holders required to provide biometrics at the air and sea ports of entry is anticipated to be approximately 24 million, comprised of approximately 19.3 million air travelers and 4.5 million sea travelers.

**Estimated Time per Response:** The average processing time per person for who biometrics will be collected is approximately one minute and fifteen seconds at entry, with 15 seconds being the additional time added for biometric collection over and above the normal inspection processing time. The average additional processing time upon exit is estimated at one minute per person. There are no additional fees for traveling aliens to pay.

**Total Burden Hours:** Approximately 100,800.

**Total Cost Burden:** None.

**Description:** The biometric information to be collected is for nonimmigrant visa holders who seek admission to the United States at the air and sea ports of entry and certain departure locations. The collection of information is necessary for the Department to continue its compliance with the mandates in section 303 of the Border Security Act, 8 U.S.C. 1732 and sections 403(c) and 414(b) of the USA PATRIOT Act, 8 U.S.C. 1365a note and 1379, for biometric verification of the identities of alien travelers and authentication of their biometric travel documents through the use of machine readers installed at all ports of entry. The arrival and departure inspection procedures are authorized by 8 U.S.C. 1225 and 1185.

Dated: March 3, 2005.

**Mark Emery,**

*Deputy, Chief Information Officer.*

[FR Doc. 05-4475 Filed 3-7-05; 8:45 am]

**BILLING CODE 4410-10-P**