

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Environmental Health Sciences; 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 Environmental Health Sciences Special Emphasis Panel, R13 Conference Grant Review.

Date: March 29, 2005.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709, (Telephone Conference Call).

Contact Person: Linda K. Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research & Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS).

Dated: March 1, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-4501 Filed 3-7-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel, Predictive Validity of Preschool Symptoms.

Date: March 9, 2005.

Time: 1 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: Victoria S. Levin, MSW, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, MSC 7848, Bethesda, MD 20892, (301) 435-0912; levinv@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Musculoskeletal Tissue Engineering.

Date: March 17-18, 2005.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jean Dow Sipe, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4106, MSC 7814, Bethesda, MD 20892, (301) 435-1743; sipej@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflicts in Motor Function, Speech and Rehabilitation.

Date: March 18, 2005.

Time: 3 p.m. to 5 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: Dana Jeffrey Plude, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7848, Bethesda, MD 20892, (301) 435-2309; pluded@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Tumor Biomarkers.

Date: March 22, 2005.

Time: 11 a.m. to 1 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: Eva Petrakova, PhD, MPH, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, (301) 435-1716; petrakoe@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, SEP Review of Macromolecular Structure and Motion Program Project Application.

Date: March 24, 2005.

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

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Gopa Rakhit, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4154, MSC 7806, Bethesda, MD 20892, (301) 435-1721; rakhitg@csr.nih.gov.

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

Date: March 24, 2005.

Time: 3 p.m. to 5 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: Rolf Menzel, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3196, MSC 7808, Bethesda, MD 20892, (301) 435-0952; menzelro@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Functional G Protein Pathways in Platelet Activation.

Date: March 25, 2005.

Time: 2 p.m. to 3:30 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: Robert T. Su, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4134, MSC 7802, Bethesda, MD 20892, (301) 435-1195; sur@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Bioinformatics Approach to Protein Phosphorylation.

Date: March 28, 2005.

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]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License: Novel Isosteric Thalidomide Analogs With Enhanced TNF- α 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- α (TNF- α), 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- α has been validated as a drug target with the development of the inhibitors Enbrel 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- α -phthalimidoglutarimide), 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- α inhibitory activity. Specifically, it inhibits TNF- α 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- α 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- α and angiogenesis activities in a subject. Disclosed analogues potentially inhibited TNF- α secretion, compared to thalidomide, via post-transcriptional mechanisms that decreased TNF- α 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