

AAG) modified at the 11 and/or 17 positions, several of which have improved solubility and altered toxicity in comparison to geldanamycin, are described in several pending NCI patent applications. NCI is seeking a licensee(s) and/or CRADA Collaborator(s) interested in continued optimization of compound pharmacology for selection of a compound to enter the clinic. Criteria for selection of a compound would include cytotoxic endpoints and regression of model tumors. Such a resulting compound(s) would be expected to have a different spectrum of activity or formulation as that for 17-AAG as described in (1) above.

3. *Optimization of Compounds for Anti-Metastatic Endpoint:* The technology for the coupled met kinase—uPA Kinase assay is described in Cancer Research 60 (2): 342–9. NCI research has defined this assay as generating lead compounds for anti-metastatic use. While encompassing some compounds from (2) above, lead compounds will have a very distinct set of development endpoints demonstrating suitability for long term chronic oral dosing, and will show evidence of activity in anti-metastasis and/or anti-angiogenesis assays without necessarily having evidence of activity in classical cytotoxic models. NCI is seeking a CRADA Collaborator(s) interested in using this assay to optimize compounds related to geldanamycin for use as anti-metastatic agents.

Party Contributions to CRADAs

The Role of the NCI in Each of the CRADAs May Include, but Not Be Limited to

1. Providing intellectual, scientific, and technical expertise and experience to the research project.
2. Providing the CRADA Collaborator with information and data relating to the CRADA technology.
3. Planning research studies and interpreting research results.
4. Carrying out research pursuant to the planned collaboration, including, but not limited to:
 - (a). Screening, pharmacology and in vivo model studies for compounds pertinent to cytotoxic endpoints;
 - (b). Assays to optimize compounds with desired pharmacology for chronic use;
 - (c). Pharmacology and determination of in vivo activity of anti-metastatic compounds;
 - (d). Production of precursors and prodrugs from fermentation sources; and
 - (e). Possible sponsorship of clinical trials of promising compounds.

5. Publishing research results.

The Role of the CRADA Collaborator May Include, but Not Be Limited to

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project, including, but not limited to:
 - (a). Structure-based design of geldanamycin analogs with suitable properties;
 - (b). Chemical modification of fermented lead structures;
 - (c). Pharmacology, toxicology, and formulation;
 - (d). Support for clinical trials in the form of drug and funding.
2. Planning research studies and interpreting research results.
3. Providing technical and/or financial support to facilitate scientific goals and to further design applications of the technology outlined in the agreement.
4. Publishing research results.

Selection Criteria for Choosing the CRADA Collaborator May Include, but Not Be Limited to

1. A demonstrated background and expertise in the preclinical and clinical development of antineoplastic agents, structure-based design, and the conduct of in vivo animal model studies pertaining to metastasis or tumor regression.
2. A demonstrated record of success in pre-clinical lead selection and optimization and/or successful clinical trials of antineoplastic therapeutics leading to a commercial product.
3. The demonstration of the necessary resources to produce sufficient drug for all clinical trials in a timely manner.
4. The ability to collaborate with NCI on further research and development of the technology. This ability will be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.
5. The demonstration of adequate resources to perform the research and development of the technology (e.g. facilities, personnel and expertise) and to accomplish the objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
6. The willingness to commit best effort and demonstrated resources to the research and development of this technology, as outlined in the CRADA Collaborator's proposal.
7. The demonstration of expertise in the commercial development and production of products related to this area of technology.

8. The ability to provide financial support for CRADA-related Government activities.

9. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

10. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.

11. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These legal provisions govern the distribution of future patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: June 25, 2001.

Kathleen Sybert,

Chief, Technology Transfer Branch, National Cancer Institute, National Institutes of Health.

Dated: June 27, 2001.

Jack Spiegel,

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

[FR Doc. 01–16762 Filed 7–3–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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: National Institute of Diabetes and Digestive Kidney Diseases Special Emphasis Panel, ZDK1 GRB-6(01).

Date: July 23-24, 2001.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Dan E. Matsumoto, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 749, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892-6600, (301) 594-8894.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB-6(04).

Date: July 24, 2001.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Dan E. Matsumoto, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 749, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892-6600, (301) 594-8894.

(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 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-16756 Filed 7-3-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious 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 section 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 Allergy and Infectious Diseases Special Emphasis Panel.

Date: July 16, 2001.

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

Agenda: To review and evaluate grant applications.

Place: 6700-B Rockledge Drive, Room 2223, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Nancy B. Saunders, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2223, 6700-B Rockledge Drive, MSC 7610, Bethesda, MD 20892-7610, 301 496-2550, ns120v@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-16757 Filed 7-3-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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 on Deafness and Other Communications Disorders Special Emphasis Panel.

Date: July 12, 2001.

Time: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: 6120 Executive Blvd., Suite 400C, Rockville, MD 20852.

Contact Person: Craig A. Jordan, PhD., Chief, Scientific Review Branch, NIH/NIDCD/DER, Executive Plaza South, Room

400C, Bethesda, MD 20892-7180, 301-496-8683.

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. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: June 26, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-16758 Filed 7-3-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, 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 Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date: July 11, 2001.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: The River Inn, 924 25th Street, Washington, DC 20037.

Contact Person: Sean O'Rourke, Scientific Review Administrator, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Suite 409, 6000 Executive Boulevard, Bethesda, MD 20892-7003, 301-443-2861.

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: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date: July 13, 2001.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.