

for consideration. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest. CRADA proposals submitted thereafter may be considered if a suitable CRADA Collaborator has not been selected.

SUPPLEMENTARY INFORMATION: In a Phase I trial, patients with hematologic malignancies and CD25 expression on malignant cells based on pre-screening immunocytochemistry and radiolabeled binding studies were given anti-Tac(Fv)-PE38 (LMB2) immunotoxin intravenously qod x 3. Thirty-two (32) patients received a total of fifty-three (53) cycles. Grade III non-hematologic toxicity was considered dose-limiting. Only 5 of the 32 patients developed significant neutralizing antibodies after the first cycle. The $T_{1/2}$ was 3–7 hours. Partial responses occurred in 5 patients including cutaneous T-cell Lymphoma, hairy cell leukemia, and chronic lymphocytic leukemia. Marginal responses were observed in two patient with Hodgkin's disease and in one patient with mantle cell lymphoma. Thus LMB-2 has activity in several forms of CD25+hematologic malignancies and is relatively non-immunogenic in this patient population.

A Cooperative Research and Development Agreement or CRADA means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer Advancement Act of 1995 to collaborate to improve the properties of Anti-Tac(Fv)-PE38. The expected duration of the CRADA would be from one (1) to five (5) years.

The role of the NCI in the CRADA may include, but not be limited to:

1. Providing sufficient amounts of anti-Tac (Fv)-PE38 (LMB2) for clinical trials.
2. Conducting Phase 2 and Phase 3 clinical trials.
3. Providing significant intellectual, scientific, and technical expertise or experience to the research project.
4. Planning research studies and interpreting research results.
5. Providing technical and/or financial support to facilitate scientific goals and for further design of applications of the technology outlined in the agreement.
6. Incorporating the immunotoxin into formulations in order to increase the therapeutic efficacy and decrease immunogenicity.

7. Providing immunotoxin for laboratory and animal studies.

8. Publishing research results. The role of the CRADA Collaborator may include, but not be limited to:

1. Providing sufficient amounts of anti-Tac (Fv)-PE38 (LMB2) for clinical trials.
2. Conducting Phase 2 and Phase 3 clinical trials.
3. Providing significant intellectual, scientific, and technical expertise or experience to the research project.
4. Planning research studies and interpreting research results.
5. Providing samples of the subject compounds to create, optimize, test and develop targeted drugs for clinical studies.
6. Providing technical and/or financial support to facilitate scientific goals and for further design of applications of the technology outlined in the agreement.
7. Incorporating the immunotoxin into formulations in order to increase the therapeutic efficacy and decrease immunogenicity.

8. Providing immunotoxin for laboratory and animal studies.

9. Publishing research results. Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NCI on further research and development of this technology. This ability can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.
2. The demonstration of adequate resources to perform the research and development of this technology (e.g., facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
3. 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.
4. The demonstration of expertise in the commercial development and production of products related to this area of technology.
5. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.
6. The demonstration of expertise pertinent to the development of models to evaluate and improve the efficacy of the anti-Tac (Fv)-PE38 (LMB2) immunotoxin for the treatment of leukemias and lymphomas.
7. The demonstration of expertise in the formulation of drugs.

8. The willingness to cooperate with the NCI in the timely publication of research results.

9. 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.

10. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the distribution of 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: October 31, 1998.

Kathleen Sybert,

Acting Director, Technology Development and Commercialization Branch, National Cancer Institute, National Institutes of Health.

Dated: October 6, 1998.

Jack Spiegel,

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

[FR Doc. 98-29989 Filed 11-6-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Meeting of the Cancer Advisory Panel for Complementary and Alternative Medicine

Notice is hereby given of the first meeting of the Cancer Advisory Panel for Complementary and Alternative Medicine (CAP), November 16, 1998, at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, Maryland 20852. The meeting is scheduled from 8:30 am to 5 pm and is open to the public. Attendance by the public will be limited to space available.

The Panel's primary responsibility is to provide expert review and evaluation of summaries of evidence for complementary and alternative medicine cancer claims by practitioners. The information compiled and evaluated by each member of the Panel will be provided to the Office of Alternative Medicine's chartered Alternative Medicine Program Advisory

Council (AMPAC) to be used during its deliberations.

The agenda includes: (1) An overview of the structure and role of the CAP; (2) a presentation on the National Cancer Institute-funded research mechanism; (3) an overview of current Office of Alternative Medicine (OAM) projects; (4) a discussion of potential future cancer clinical trials initiatives related to complementary and alternative medicine; and (5) a public comment session.

The public comment session is scheduled from 3 p.m. to 5 p.m. Each speaker will be permitted 5 minutes for their presentation. Interested individuals and representatives of organizations are requested to notify D. Geoffrey Cheung, Office of Alternative Medicine, NIH, 31 Center Drive, (MSC 2182), Building 31, Room 5B37, Bethesda, MD 20892, (301) 594-2013, FAX: (301) 594-6757. Letters of intent to present comments, along with a brief description of the organization represented, should be received no later than 5:00 p.m. on Thursday, November 12. Only one representative of an organization may present oral comments. Any person attending the meeting who does not request an opportunity to speak in advance of the meeting may be considered for oral presentation, if time permits, and at the discretion of the Chairperson. In addition, written comments may be submitted to Dr. Geoffrey Cheung at the address listed above up to ten days following the meeting.

For additional information please contact Ms. Odessa Colvin, Program Assistant, OAM, 31 Center Drive, MSC 2182, Building 31, Room 5B37, Bethesda, Maryland, 20892, (301-435-5175). Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Colvin in advance of the meeting.

Dated: November 2, 1998.

Ruth L. Kirschstein,
Deputy Director, National Institute of Health.
[FR Doc. 98-29984 Filed 11-6-98; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice

is hereby given of a meeting of the President's Cancer Panel.

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.

Name of Committee: President's Cancer Panel.

Date: November 17, 1998.

Time: 8 AM to 5 PM.

Agenda: Cancer Prevention in the 21st Century.

Place: Arizona Cancer Center, Kiewit Conference Room, 1515 North Campbell Avenue, Room 2851, Tucson, AZ 85724.

Contact Person: Maureen O. Wilson, Executive Secretary, National Cancer Institute, National Institutes of Health, 31 Center Drive, Building 31, Room 4A48, Bethesda, MD 20892.

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.

(Catalog of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 2, 1998.

LaVerne Y. Stringfield,
Committee Management Officer, National Institutes of Health.

[FR Doc. 98-29987 Filed 11-6-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Review Group, Subcommittee D—Clinical Studies.

Date: November 30–December 1, 1998.

Time: 8 AM to 6 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Martin H. Goldrosen, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, room 635 C, Rockville, MD 20852-7408, (301) 496-7930.

(Catalogue of Federal Domestic Assistance Program Nos. 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control; 93.392, Cancer Construction, National Institutes of Health, HHS)

Dated: November 2, 1998.

LaVerne Y. Stringfield,
Committee Management Officer, National Institutes of Health.

[FR Doc. 98-29988 Filed 11-6-98; 8:45 am]

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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. 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 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 Drug Abuse Special Emphasis Panel Research Dissemination to the Entertainment Industry Communities.

Date: November 10, 1998.

Time: 9 AM to 4 PM.

Agenda: To review and evaluate contract proposals.

Place: Ramada Inn Rockville, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Program Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 5600