

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.
STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202-452-3204.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: February 11, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00-3781 Filed 2-14-00; 10:51 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Development of Idiotypic Tumor Vaccines for Treatment of B-Cell Lymphoma

An Opportunity for a Cooperative Research and Development Agreement (CRADA) is available for collaboration with the NCI Intramural Division of Clinical Sciences for the support of Phase III clinical trials evaluating the efficacy of a protein-based immunoglobulin idiotype vaccine in the treatment of low-grade follicular B-cell lymphoma.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of opportunities for Cooperative Research and Development Agreements.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. § 3710; Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public

Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks a Cooperative Research and Development Agreement (CRADA) with a pharmaceutical or biotechnology company. Any CRADA for development of this technology that includes support for vaccine production, monitoring of Phase III clinical trials and data analysis, or any combination of the above will be considered. The CRADA would have an expected duration of five (5) to seven (7) years. The goals of the CRADA will include the rapid publication of research results and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborators will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADA.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Karen Muszynski, Technology Development & Commercialization Branch, National Cancer Institute—Frederick Cancer Research and Development Center, Fairview Center, 1003 West Seventh Street, Room 502, Frederick, MD 20852, Telephone: (301) 846-5222; Facsimile: (301) 846-6820.

EFFECTIVE DATE: Organizations must submit a proposal summary preferably one page or less, to NCI within 90 days from date of this publication. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial discussions will have established sufficient mutual interest.

SUPPLEMENTARY INFORMATION:

Technology Available

The National Cancer Institute (NCI) of the National Institutes of Health (NIH) has initiated an FDA-approved, multi-institutional Phase III clinical trial of protein-based immunoglobulin idiotype vaccines for the treatment of low-grade follicular B-cell lymphoma. B-cell tumors are composed of clonally-expanded cells synthesizing a single antibody molecule containing unique variable regions known as idiotypic determinants. The idiotypic determinants of B-cell derived tumors comprise tumor-specific antigens that can serve as a target for immunotherapy. The NCI has previously conducted Phase I and Phase II clinical trials to determine if therapeutically significant immune responses against an autologous, idiotype immunoglobulin protein can be induced in B-cell lymphoma patients (Nature Medicine

5:1171-1177, Oct 1999). Based on results from these studies, the Clinical Research Branch of the NCI has initiated a definitive multi-center Phase III clinical trial of idiotype-specific vaccines for the treatment of low-grade follicular B-cell lymphoma. The NCI, in accordance with the regulations governing the transfer of agents which the Government has taken an active role in developing (37 CFR 404.8), is seeking a pharmaceutical or biotechnology company which can develop these vaccines to a commercially available status to meet the needs of the public and with the best terms for the government.

The NCI specifically seeks a collaborator to support vaccine production and clinical monitoring of the NCI-sponsored Phase III clinical trials in anticipation of the successful commercialization of this technology. Since idiotypic determinants are tumor-specific, the vaccines must be custom-made for each patient. The selected sponsor will collaborate in the development and production of GMP certifiable idiotype vaccines for the treatment of follicular B-cell lymphomas to be used in the Phase III clinical trials leading to a New Drug Application or Biological License Application for a new anti-cancer therapy in anticipation of the successful commercialization of this product. A specific goal of this CRADA will be development of the processes required for large-scale GMP vaccine production and the provision of adequate numbers of GMP produced and formulated idiotype vaccines as needed to complete the clinical development of this agent for the treatment of follicular B-cell lymphoma. The collaborator will be selected based on their ability to provide specific expertise in conversion to GMP vaccine production; experience in preclinical and clinical drug development; experience in the monitoring, evaluation and interpretation of data from investigational agent clinical studies under an IND; and experience in the successful commercialization, marketing and distribution of new cancer therapy products.

The role of the National Cancer Institute in this CRADA may include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience related to the development of idiotype vaccines.

2. Conducting a Phase III clinical trial to evaluate the therapeutic efficacy of idiotype vaccines in association with GM-CSF.

3. Providing scientific and technical expertise in immunological and

molecular monitoring of patient responses to the vaccines.

4. Maintenance of an Investigational New Drug Application (IND), including but not limited to submission of Annual Reports, adverse drug experience reports, new protocols, protocol amendments and pharmaceutical data.

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 development of processes required for large-scale GMP vaccine production.

2. Provide adequate quantities of GMP certifiable idiotypic vaccines for use in the NCI-sponsored Phase III clinical trial, including all necessary pre-clinical safety information and preparation, filing, and submissions to the Drug Master File or IND as required for clinical studies.

3. Providing technical and financial support to facilitate scientific goals, clinical trial monitoring and data analysis.

4. Collaborate in clinical development leading to FDA approval and marketing through participation on a Steering Committee established to guide the commercialization effort.

5. Assume responsibility for the commercialization, marketing and distribution of the vaccine following successful completion of the Phase III trials.

6. 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 the research and development of this technology. The ability to collaborate with NCI 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 willingness to cooperate with the National Cancer Institute in the timely publication of research results.

7. 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.

8. The willingness to accept the legal provisions and language of the CRADA with only minor modification, 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: February 7, 2000.

Kathleen Sybert,

Branch Chief, Technology Development & Commercialization Branch, National Cancer Institute, National Institutes of Health.

[FR Doc. 00-3591 Filed 2-15-00; 8:45 am]

BILLING CODE 4140-01-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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)(94) 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 Center for Research Resources Special Emphasis Panel, Comparative Medicine.

Date: February 17, 2000.

Time: 8 am to Adjournment.

Agenda: To review and evaluate grant applications.

Place: The Bethesda Ramada, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Camille M. King, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965, 301-435-0815.

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. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: February 8, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-3587 Filed 2-15-00; 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 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 of 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: March 6-8, 2000.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Arlington, Hotel, Salon A Room, 1325 Wilson Blvd., Arlington, VA 22209.

Contact Person: Kevin W. Ryan, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2217, 6700-B Rockledge Drive, MSC 7610, Bethesda, MD 20892-7610, 301-496-2550.

(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)