ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks a pharmaceutical company that can effectively pursue the clinical development of Homoharringtonine for the treatment of cancer. The National Cancer Institute has established that this agent may be effective in treating several types of cancers. The selected sponsor will be awarded a CRADA for the development of this agent.

The term of the CRADA is anticipated to be three (3) to five (5) years.

ADDRESSES: Questions about this opportunity may be addressed to Mike Christini, J.D. or Michelle Rhyu, Ph.D., Office of Technology Development, NCI, Building 31, Bethesda, Maryland 20892 (301) 496–0477, from whom further information including a summary copy of the preclinical and clinical data may be obtained.

DATES: In view of the important priority of developing new drugs for the treatment of cancer, proposals must be received at the above address by 5 pm December 18, 1995.

SUPPLEMENTARY INFORMATION: 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 October 10, 1987 to collaborate on the specific research project described below. Under the present proposal, the Government is seeking a pharmaceutical company, which in accordance with the requirements of the regulations governing the transfer of technology that the Government has taken an active role in developing (37 CFR 404.8), can further develop Homoharringtonine to a marketable status to best meet the needs of the public. The government does not hold any active patents for this compound.

Homoharringtonine is a cephalotaxine ester isolated from the cephalotaxus evergreen indigenous to China. It has shown promising activity in patients with chronic myelogenous leukemia (CML). Clinical development directed toward licensing includes confirmatory phase 2 trials of HHT in combination with other agents with demonstrated activity in CML and a phase 3 trial of HHT against standard therapy in refractory CML.

The Division of Cancer Treatment, NCI, is interested in establishing a CRADA with a pharmaceutical company to assist in the continuing development of the agent. The Government will provide all available expertise and information to date and will jointly pursue new clinical studies as required, giving the pharmaceutical company full access to existing data and data developed pursuant to the CRADA.

The successful pharmaceutical company will provide the necessary financial and organizational support to complete further development of this agent to establish clinical efficacy and possible commercial status.

The role of the Division of Cancer Treatment, NCI, includes the following:

1. The Government will provide information concerning pharmaceutical manufacturing and controls including dosage development data.

2. The Government will allow the pharmaceutical company to review and cross-file the Division's IND for the agent; it is likely that the pharmaceutical company would wish to undertake clinical studies independently, as well as jointly under the CRADA.

3. The Government will make the Division's IND for the agent proprietary under the terms of the CRADA and the IND data will be offered exclusively to the selected pharmaceutical company.

4. The DCT, NCI will make the collaborator its sole and exclusive commercialization partner for the development of this compound.

5. The Government will continue the preclinical and clinical development of this agent under its extramural clinical trials network.

The role of the successful pharmaceutical company for the agent under a CRADA will include the following:

1. Provide and implement plans to independently secure future supplies of the agent to assure continued preclinical and clinical development. The pharmaceutical company will provide for the costs of production of Homoharringtonine produced from the date of this Notice until such time as the company shall assume responsibility for satisfying the supplies required by the Division of Cancer Treatment, NCI.

2. Generate a plan and provide financial and regulatory support for the clinical development leading to FDA approval for marketing.

3. In the development of compounds derived from natural products, the NCI is concerned that the utilization of the plant material comport with all applicable laws and policies in the source country related to biodiversity. It is the responsibility of the CRADA partner to negotiate and enter into agreements with source country agencies as appropriate to address these concerns.

Criteria for choosing the pharmaceutical company include the following:

1. Experience in the preclinical and clinical development of anticancer agents.

2. Experience and ability to produce, package, market and distribute pharmaceutical agents in the United States.

3. Experience in the monitoring, evaluation and interpretation of the data from investigational agent clinical studies under an IND.

4. A willingness to cooperate with the Public Health Service in the collection, evaluation, publication and maintenance of data from clinical trials of investigational agents.

5. A willingness to cost share in the development of the agent. This includes the acquisition of bulk material and formulation of clinical products in adequate amounts as needed for future clinical trials and marketing, as well as the partial funding of regulatory costs and personnel dedicated to completion of the CRADA research project.

6. An agreement to be bound by the DHHS rules involving human and animal subjects.

7. Formulation of an aggressive clinical development plan, including appropriate milestones and deadlines.

8. Provisions for equitable distribution of patent rights to any inventions. Generally the rights of ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government (when a company employee is the sole inventor) or (2) an option to an exclusive or nonexclusive license to the company on terms that are appropriate (when the Government employee is the sole inventor).

9. Willingness and ability to acquire any necessary background patent rights.

10. Submission of an initial response to the NIH Model Clinical Trial CRADA boilerplate provisions.

Dated: October 6, 1995.

Thomas D. Mays,

Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

[FR Doc. 95–25731 Filed 10–16–95; 8:45 am]

BILLING CODE 4140–01–P

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting Girish C. Barua, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7735 ext 263; fax 301/402–0220). A signed Confidential Disclosure Agreement will be required to receive a copy of the patent application.

Antibacterial Therapy With Bacteriophage Genotypically Modified To Delay Inactivation by the Host Defense System

Carlton, R., Merril, C., Adhya, S.
Filed 5 Apr 94
Serial No. 08/222,956

The present invention is directed to bacteriophage therapy, using methods that enable the bacteriophage to delay inactivation by any and all parts of the host defense system (HDS) against foreign objects that would tend to reduce the numbers of bacteriophage and/or the efficiency of those phage at killing the host bacteria in an infection. Disclosed is a method of producing bacteriophage modified for anti-HDS purposes, one method being selection by serial passaging, and the other method being genetic engineering of a bacteriophage, so that the modified bacteriophage will remain active in the body for longer periods of time than the wild-type phage. [portfolio: Infectious Diseases—Therapeutics]

Dated: October 4, 1995.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 95–25730 Filed 10–16–95; 8:45 am]

BILLING CODE 4140–01–P

Notice of Meeting

Notice is hereby given of the meeting of the NIH AIDS Research Program Evaluation Working Group Area Review Panel on Clinical Trials on November 13–14, 1995 at the Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, Maryland. The meeting will be open to the public from 8:00 a.m. to 12:00 p.m. on November 13, and the closed portions will be from 1:00 p.m. to 5:30 p.m. on November 13, and 8:30 a.m. to 3:00 p.m. on November 14.

The NIH Revitalization Act of 1993 authorizes the Office of AIDS Research (OAR) to evaluate the AIDS research activities of NIH. The NIH AIDS Research Program Evaluation Working Group was established by the OAR to carry out this major evaluation initiative, reviewing and assessing each of the components of the NIH AIDS research endeavor to determine whether those components are appropriately designed and coordinated to answer the critical scientific questions to lead to better treatments, preventions, and a cure for AIDS. Six Area Review Panels were also established to address the following research areas: Natural History and Epidemiology; Etiology and Pathogenesis; Clinical Trials; Drug Discovery; Vaccines; and Behavioral and Social Sciences Research.

The purpose of the meeting is to seek input from individuals and organizations interested in the evaluation of AIDS research in the areas of therapeutics research as it pertains to clinical trials. Examples of areas under consideration by the panel include the effectiveness, efficiency, scientific productivity and clinical impact of NIH clinical trials programs in adults and children for HIV and its sequelae. This includes trials aimed at improving outcomes by limiting HIV replication and enhancing immune function as well as studies aimed at preventing and treating the complications of advanced HIV disease. The NIH Aids Research Program Evaluation Working Group will develop recommendations to be made to the Office of AIDS Research Advisory Council that address the overall NIH AIDS research initiatives, both intramural and extramural, and identify long-range goals in the relevant areas of science. These recommendations will provide the framework for future planning and budget development of the NIH AIDS research program.

There will be a closed session from 1:00 p.m. to 5:30 p.m. on November 13 and 8:30 a.m. to 3:00 p.m. on November 14, to update the Panel members on privileged information on institute and center grant and contract portfolios.

The open session from 8:00 a.m. to 12:00 p.m. will begin with a brief overview of panel activities by members of the panel. The remainder of the meeting will be devoted to presentations from individuals and organizations. The session is open to the public; however, attendance may be limited by seat availability.

Comments should be confined to statements related to the current status of NIH AIDS research in the areas of therapeutic clinical trials and recommendations for consideration by the panel in assessing and reviewing the relevant research in these areas.

Only one representative of an organization may present oral comments. Each speaker will be permitted 5 minutes for their presentation. Interested individuals and representatives of organizations must submit a letter of intent to present comments and three (3) typewritten copies of the presentation, along with a brief description of the organization represented, to the attention of Dr. Judith Feinberg, Office of AIDS Research, NIH, 31 Center Drive, MSC 2340, Building 31, Room 5C08, Bethesda, MD 20892–2340, (301) 496–0358, FAX: (301) 402–8638. Letters of intent and copies of presentations must be received no later than 5:00 p.m. on Monday, October 30.

Any person attending the meeting who does not request an opportunity to speak in advance of the meeting will be allowed to make a brief oral presentation at the conclusion of the meeting, if time permits, and at the discretion of the Chairperson.

Individuals wishing to provide only written statements should send three (3) typewritten copies of their comments, including a brief description of their organization, to the above address no later than 5 p.m. on October 30. Statements submitted after that date will be accepted. They may not, however, be made available to the Area Review Panel prior to the meeting, though they will be provided subsequently as written testimony.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Feinberg in advance of the meeting.

Dated: October 11, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–25729 Filed 10–16–95; 8:45 am]

BILLING CODE 4140–01–M

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 National Center for Research Resources Special Emphasis Panel (SEP) meeting: