DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Development of Anti-CD30 Monoclonal Antibody; for the Development of HeFi–1, Cooperative Research and Development Agreement

National Cancer Institute: Development of Anti-CD30 monoclonal antibody: Opportunity for Cooperative Research and Development Agreement (CRADA) for the development of HeFi–1, a murine antibody that targets the CD30 transmembrane receptor expressed on activated B and T lymphocytes and some tumor cells. Development activities will include the humanization and/or chimerization of HeFi–1, followed by the pre-clinical and clinical development of the antibody. In addition, clinical studies of the murine HeFi–1 are also anticipated under this CRADA.

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice for CRADA Opportunity.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and 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 to develop a new treatment for CD30 positive tumors including Hodgkin's Disease non-Hodgkin's lymphomas. The CRADA would have an expected duration of four (4) years. The goals of the CRADA include the rapid humanization and/or chimerization of the antibody for clinical trials and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborator will have an option to an exclusive commercialization license in a pre-determined field of use to subject inventions arising under the CRADA Research Plan.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to: Dr. Suzanne Frisbie, Technology Development & Commercialization Branch, National Cancer Institute, 6120 Executive Boulevard Suite 450, Rockville, MD 20852 (phone: 301–435–3113, fax: 301–402–2117).

EFFECTIVE DATE: Inquiries regarding CRADA proposals and scientific matters may be forwrded at any time. Confidential CRADA proposals, preferably two pages or less, must be submitted to the NCI within 30 days from date of this publication. Guidelines for preparing a full CRADA proposal will be communicated shortly thereafter to the respondent who has been selected.

SUPPLEMENTARY INFORMATION:

Technology Available

DHHS scientists at the NCI have developmed a murine monoclonal antibody, HeFi–1, that targets CD30, a 120 kD transmembrane protein from the tumor necrosis receptor family that is expressed on activated B and T cells. In addition, CD30 expression has been detected on Band T cell lymphomas, Epstein-Barr virus-infected lymphoblastoid cells, HIV-associated lymphomas, Reed-Sternberg cells from Hodgkin's Lymphomas, embryonal carcinoma cells and carcinoma cells of the rhino-pharynx (Schmincke's tumor). Expression of either the CD30 receptor of fragments of CD30 has been identified as a negative prognostic sing in Hodgkin's Lymphoma. In vitro experiments have demonstrated that binding of the CD30 ligand can induce cells to proliferate, differentiate or undergo apoptosis, depending on the cell line. The potential usefulness of CD30 as an anti-tumor agent has been established in murine xenograft models. In mice treated with HeFi–1 following injection of Anaplastic Large Cell Lymphoma cells, no evidence of tumor was detected at day 60 in contrast to a median survival of 39 days for control animals. The NCI is interested in developing HeFi–1 as an anti-tumor agent for the treatment of human disease and is soliciting proposals for humanization and/or chimerization of the antibody using standard molecular techniques.

The successful Collaborator must have extensive, documented experience in the humanization and/or chimerization of murine-derived antibodies suitable for use in clinical trials. The product must retain the same or better affinity for binding to CD30 as the original HeFi–1 antibody and the producer cell line must secrete the antibody at a high enough rate to make it cost effective for use in large-scale production. The Collaborator will be responsible for verifying that the humanized and/or chimerized antibody binds the appropriate target protein and the final product must be stable and not aggregate. The NCI will provide the original cell line producing the murine antibody to the Collaborator.

For collaborations with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide equitable distribution of intellectual property rights developed under the CRADA. CRADA aims will include rapid humanization and/or chimerization of the antibody for clinical trails as well as full and timely exploitation of any commercial opportunities.

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

1. Providing intellectual, scientific, and technical expertise and experience to the research project.

2. Providing the Collaborator with the original cell line producing the murine HeFi–1 antibody.

3. Planning research studies and interpreting research results.

4. Support and sponsorship of clinical trails to evaluate efficacy and safety of product.

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

1. Providing significant intellectual, scientific, and technical expertise in the development and production of humanized antibodies and in the pre-clinical and clinical development of the antibody.

2. Ability to collaborate with the NCI in the development of and conduct of assays to assure that the final product conforms to the technical requirements for use of the antibody in clinical trials and make all data available to the NCI.

3. Providing technical expertise and/or financial support (e.g. facilities, personnel and expertise) for CRADA-related activities.

4. Accomplishing objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

5. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.

6. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of technology.

7. The willingness 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 modifications, if any. These provisions govern the equitable distribution of patent rights to CRADA inventions.

9. The ability to obtain licensing or background rights if required for commercialization of the humanized and/or chimerized HeFi–1 antibody. NCI is currently not aware of any relevant patents that would need to be licensed for this CRADA opportunity, however NCI does not warrant that no such patents exist.

Dated: June 3, 1999.

Kathleen Sybert,

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

[FR Doc. 99–15226 Filed 6–15–99; 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 Special Emphasis Panel Oncogenes in Cancer Etiology and Progression.

Date: June 25, 1999.

Time: 1 PM to 3 PM.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Blvd. 6th Floor, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: David Irwin, PHD., Research Programs Review Section Chief, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institute of Health, 6130 Executive Boulevard, EPN-Room 635E, Rockville, MD 20892–7405, (301) 402–0371.

(Catalogue 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: June 8, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

[FR Doc. 99–15227 Filed 6–15–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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Name of Committee: National Cancer Institute Special Emphasis Panel, Phase III: Trial of Lycopene and Selenium in Prostrate Cancer and Selenium and Vitamin E Chemprevention Trial.

Date: June 30, 1999.

Time: 9 AM to 4:30 PM.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Boulevard, Room 635, Rockville, MD 20852.

Contact Person: Mary C Fletcher, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, EPN—Room 643G, Bethesda, MD 20814, 301/496–7413.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.939, 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: June 8, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

[FR Doc. 99–15228 Filed 6–15–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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Name of Committee: National Cancer Institute Special Emphasis Panel, Transdisciplinary Tobacco Use Research Centers.

Date: July 7–9, 1999.

Time: 7 PM to 6 PM.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites, Chevy Chase Pavilion, 4300 Military Rd., Wisconsin at Western Ave., Washington, DC 20015.

Contact Person: Gerald G. Lovinger, PHD., Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard/EPN—Room 630D, Rockville, MD 20892–7405, 301/496–78987.

(Catalogue 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: June 8, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

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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