Subject, city, state	Effective date
Peart, John A, Fresno, CA	11/19/1998
Pessu-Uwah, Audrey O, New Castle, DE	11/19/1998
Porter, Rodney Wayne, Corning, AR	11/19/1998
Pyne, Keith E, Dallas, TX	11/19/1998
Rapena, Robert J, Jackson Hgts, NY	11/19/1998
Reed, Fred Lee, Jr, Long Beach, CA	11/19/1998
Reich, Stephen Geffry, Owings Mills, MD	11/19/1998
Rodriguez, Robert L, San Antonio, TX	11/19/1998
Rodriguez, Joe Henry, Dallas, TX	11/19/1998
Root, Richard A, Grand Rapids, MI	11/19/1998
Rusk, Kent A, Denmark, WI	11/19/1998
Russell, Michael R, Newburyport, MA	11/19/1998
Sabir, Rafiq Abdus, New York, NY	11/19/1998
Shay, Fred G, Chandler, AZ	11/19/1998
Smith, Rusty A, Santa Barbara, CA	11/19/1998
Snook (Allen), Debra Lynn, Dodge City, KS	11/19/1998
Staton, Sonya E, Newton, MA	11/19/1998
Stewart (Carballo), Charles W, Fayetteville, NC	11/19/1998
Terrian, Robert Joseph, Bedford, TX	11/19/1998
Torres, Jerry, Espanola, NM	11/19/1998
Tyrrel, Robert TY, Atlanta, GA	11/19/1998
Worthy, Edwin, Jr, Roxbury, MA	11/19/1998
Yoder, Terry E, Belton, MO	11/19/1998
OWNERS OF EXCLUDED ENTITIES	
Graham, Marva C, Columbia, MD	11/19/1998

Dated: November 2, 1998.

Joanne Lanahan,

Director, Health Care Administrative Sanctions, Office of Inspector General.

[FR Doc. 98–29935 Filed 11–6–98; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Licensing Opportunity and/or Cooperative Research and Development Agreement (''CRADA'') Opportunity: Drug and Method for the Therapeutic Treatment of Leukemia, Lymphoma, Hairy Cell Leukemia, Hodgkin's Disease, and Other Hematologic Malignancies

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The NIH is seeking Licensees to further develop, evaluate, and commercialize anti-Tac (Fv)–PE38, also known as LMB2, immunotoxin for the therapeutic treatment of refractory Leukemia, Lymphoma, Hairy Cell Leukemia, Hodgkin's disease and other hematologic malignancies. Anti-Tac (Fv)–PE38 (LMB2) is a recombinant immunotoxin composed of a single-chain Fv form of the anti-Tac (anti-CD25) monoclonal antibody, which binds to the α subunit of the IL2 receptor (also called P55, Tac, or CD25), fused to PE38, a mutant form of *Pseudomonas* Exotoxin A. Anti-TAC (Fv)–PE38 (LMB2) is very cytotoxic to normal or malignant cells expressing IL2 receptors and is being developed for the therapy of chronic lymphocytic leukemia, lymphoma, Hodgkin's disease and Hairy Cell Leukemia. The goal is to move the Anti-Tac (FV)–PE38 (LMB2) immunotoxin into Phase II and III clinical trials. The inventions claimed in USPN 4,892,827, entitled: ''Recombinant *Pseudomonas* Exotoxins: Construction of an Active Immunotoxin with Low Side Effects''; USSN 07/865,722, entitled: ''Recombinant Antibody-Toxin Fusion Protein''; USPN 5,696,237, entitled: ''Recombinant Antibody-Toxin Fusion Protein''; and USSN 08/461,825, entitled: ''Recombinant Antibody-Toxin Fusion Protein''; are available for either exclusive or non-exclusive licensing for these aforementioned applications only (in accordance with 35 U.S.C. 207 and 37 CFR Part 404).

ADDRESSES: Questions about licensing opportunities may be addressed to J.R. Dixon, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; Telephone: (301)–496–7056 ext. 206; Facsimile: (301)–402–0220; E-Mail: ''DixonJ@OD.NIH.GOV''. Information about Patent Applications and pertinent information not yet publicly described can be obtained under the terms of a Confidential Disclosure Agreement. Respondees interested in licensing the invention(s) will be required to submit an ''Application for License to Public Health Service Inventions''.

Depending upon the mutual interests of the Licensee(s) and the NCI, a Cooperative Research and Development Agreement (CRADA) to collaborate to improve the properties of the Anti-Tac (Fv)–PE38 may also be negotiated. Proposals and questions about this CRADA opportunity may be addressed to Dr. Patrick Twomey, Technology Development Specialist, Technology Development & Commercialization Branch, National Cancer Institute, 6120 Executive Plaza South-Room 450, Rockville, Maryland 20852; Telephone: (301)–496–0477; Facsimile: (301)–402–2117; email: twomeyp@OTD.NCI.NIH.GOV. Respondees interested in submitting a CRADA Proposal should be aware that it may be necessary to secure a license to the above-mentioned patent rights in order to commercialize products arising from a CRADA.

EFFECTIVE DATE: Respondees interested in licensing the invention(s) will be required to submit an ''Application for License to Public Health Service Inventions'' on or before January 8, 1999 for priority consideration.

Interested CRADA collaborators must submit a confidential proposal summary to the NCI [attention Dr. Patrick Twomey at the aforementioned address] on or before January 8, 1999,

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 trails.
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]

BILLING CODE 4140–01–M

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