

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of extension of announcement.

SUMMARY: The National Cancer Institute (NCI) seeks a Cooperative Research and Development Agreement (CRADA) with a software company with demonstrated excellence in the development and deployment of software applications for the enterprise and individuals. NCI has recently developed a powerful but user-friendly computer-based system which enables its users to create, use and share a knowledge base of information consisting of diverse objects related to each other by semantically meaningful links. This system, provisionally called "KBTool", can be considered a new class of software application since it is sufficiently different from existing applications. The system provides a knowledge base that is seamless, allowing individuals to store information on a virtually unlimited range of objects and concepts. In addition, dense and informative links between many types of concepts are constructed. The system is extensible so that it is suited for use in distributed systems in which information is shared between users and stored at different physical locations. Because of the power of the system and its relevance to many domains of knowledge and types of applications, the NCI is seeking a commercial partner for its continued development and deployment. The software was originally created to organize and link vast quantities of scientific data; however, NCI predicts that KBTool's functionality will be applicable to a wide variety of fields. The Collaborator must have a demonstrated record of success in privately producing and marketing information resources. Please refer to **Federal Register** notice number 74, volume 64, page 19183, dated April 19, 1999 for additional information about the KBTool technology and the corresponding CRADA opportunity.

A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into by the 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. The NCI is looking for a CRADA partner to collaborate in the development of the properties of the KBTool data management system. The expected duration of the CRADA would be from one(1) to five (5) years.

DATES: Interested parties should notify this office in writing of their interest in filing a formal proposal no later than July 21, 1999. They will then have an additional thirty (30) days to submit a formal proposal. CRADA proposals submitted thereafter may be considered if a suitable CRADA Collaborator has not been selected.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to Holly S. Symonds, Ph.D. (Tel. #301-496-0477, FAX # 301-402-2117), Technology Development and Commercialization Branch, National Cancer Institute, 6120 Executive Blvd., Suite 450, Rockville, MD 20852. Inquiries directed to obtaining patent license(s) needed for participation in the CRADA opportunity may be addressed to John Fahner-Vihtelic, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852, (Tel. 301-496-7735, ext. 270; FAX 301-402-0220).

Dated: June 13, 1999.

Kathleen Sybert,

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

[FR Doc. 99-15637 Filed 6-18-99; 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: Licensing Opportunity and/or Cooperative Research and Development Agreement ("CRADA") Opportunity; Drug and Method for the Therapeutic Treatment of Respiratory Syncytial Virus and Parainfluenza Virus in Children

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID) of the NIH is seeking Licensees and/or capability statements from parties to further develop, evaluate, and commercialize eosinophil-derived neutralizing agent (EDNA) for the treatment of infections in children and/or the elderly caused by Respiratory Syncytial Virus (RSV) and parainfluenza virus (PIV). RSV and PIV are medically the most important single-stranded RNA viruses; infections caused by these viruses hospitalize over 100,000 infants per year in the U.S.

The methods and compositions of this invention provide a means for prevention and treatment of infection by enveloped RNA viruses by eosinophil derived neutralizing agent (EDNA), a ribonuclease. EDNA is a relatively soluble and thermostable protein, active at low concentrations, with no direct toxicity to bronchial epithelial cells, making it suitable for inhalation therapy. Parenteral administration is also contemplated by this invention.

EDNA, particularly recombinant EDNA, may be used as an agent for direct inhalation therapy in children with established RSV bronchiolitis (associated with the development of future respiratory disorders such as asthma), in children for which there is a high index of suspicion, and as prophylactic therapy in children with predisposing conditions such as prematurity, bronchiole pulmonary dysplasia, congenital heart disease and immunodeficiency. Similar criteria may be applied to the susceptible elderly population.

Recombinant human EDNA has been produced in bacterial and baculovirus expression systems. Furthermore, in vitro experiments have shown it to have potent antiviral activity against RSV (Domachowske, JB et al., 1998, *J. Infect. Dis.* 177:1458-1464.) Initial studies in the Balb/C mouse model of RSV infection support its effectiveness against this virus. This project is a part of the study of ribonucleases and host defenses in the Laboratory of Host Defenses (LHD), Division of Intramural Research, NIAID.

The invention claimed in DHHS Reference No. E-161-97/1, "Methods for Inactivating Enveloped RNA Virus Particles and Compositions for Use Therewith" (HF Rosenberg, JB Domachowske), PCT/US98/13852 filed July 2, 1998, is available for exclusive or non-exclusive licensing in accordance with 35 U.S.C. 207 and 37 CFR part 404 and/or further development under one or more CRADAs in the clinically important applications described below in the Supplementary Information section.

ADDRESSES: Questions about licensing opportunities should be addressed to Peter Soukas, J.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. 268; Facsimile: (301) 402-0220; E-mail: ps193c@nih.gov. Information about Patent Applications and pertinent information not yet publicly described can be obtained under the terms of a

Confidential Disclosure Agreement. Respondents interested in licensing the invention 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 NIAID, a CRADA to collaborate to develop EDNA as an anti-RSV therapeutic may also be negotiated. Proposals and questions about this CRADA opportunity should be addressed to Dr. Michael R. Mowatt, Technology Development Manager, Office of Technology Development, NIAID, Building 31, Room 3B62, 31 Center Drive, Bethesda, MD 20892-2137, Telephone: (301) 435-8618; E-mail: mm25q@nih.gov. Respondents 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: Respondents interested in licensing the invention will be required to submit an "Application for License to Public Health Service Inventions" on or before September 20, 1999, for priority consideration.

Interested CRADA collaborators must submit a confidential proposal summary to the NIAID [attention Dr. Michael Mowatt at the aforementioned address] on or before September 20, 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 and PHS License Applications submitted thereafter may be considered if a suitable CRADA collaborator of Licensee(s) has not been selected.

SUPPLEMENTARY INFORMATION: Under the CRADA the production of biologically active recombinant human EDNA will be optimized and the agent evaluated in a series of preclinical studies in animals as well as initial safety testing in humans. Positive outcomes of these studies will indicate continued clinical development aimed at supporting regulatory approval of a product to be labeled for use in children and/or the elderly. The Public Health Service (PHS) has filed patent applications both in the U.S. and internationally related to this technology. Notice of the availability of the patent application for licensing was first published in the **Federal Register** (Vol. 62, No. 219, Page 60909) on November 13, 1997.

NIAID's principal investigator has extensive experience with recombinant technology as applied to ribonucleases, their purification and testing. The

Collaborator in this endeavor is expected to assist NIAID in evaluating its current system for producing recombinant EDNA and to develop and optimize an alternative expression system, if necessary, to manufacture sufficient quantities of the product for preclinical testing in animals and initial safety studies in humans. The Collaborator must have experience in the manufacture of recombinant protein products according to applicable FDA guidelines and Points to Consider documents to include Good Manufacturing Procedures (GMP). In addition, it is expected that the Collaborator would provide funds to supplement the LHD's research budget for the project and to support the preclinical and initial human testing.

The capability statement should include detailed descriptions of: (1) Collaborator's expertise in the expression of recombinant proteins, (2) Collaborator's ability to manufacture sufficient quantities of the product according to FDA guidelines and Points to Consider documents, (3) the technical expertise of the Collaborator's principal investigator and laboratory group in preclinical safety testing (e.g., expertise in *in vitro* and *in vivo* toxicity and pharmacology studies) and initial human safety studies, and (4) Collaborator's ability to provide adequate funding to support preclinical and initial human safety studies required for marketing approval.

Dated: May 24, 1999.

Mark Rohrbaugh,

Director, Office of Technology Development,
National Institute of Allergy and Infectious Diseases.

Dated: June 10, 1999.

Jack Spiegel,

Director, Division of Technology Development
and Transfer, Office of Technology Transfer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are 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 companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting Susan S. Rucker, J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7056 ext. 245; fax: 301/402-0220; e-mail: sr156v@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Transgenomic Viruses

WJ Ramsey, RM Blaese, KG Xanthopoulos (NHGRI)

Serial No. 09/058,686 filed April 10, 1998, PCT/US98/07166 filed April 9, 1998 and 60/043,667 filed April 11, 1997.

Licensing Contact: Susan S. Rucker, 301/496-7056 ext 245

The technology described and claimed in these applications relates to the fields of gene therapy, the production of transgenic non-human animals and diagnostic or quality control applications where identification of an unknown viral genome is desired. More, particularly the technology described and claimed in the application relates to chimeric viruses. When used for gene therapy or the production of transgenic non-human animals the chimeric viruses are capable of producing secondary virus in a producer cell. The secondary virus may be any virus other than the primary virus or a Dependovirus. When used for diagnostic or quality control applications the chimeric virus complements, *in trans*, the secondary packaging components found in the producer cells.

When employed in the fields of gene therapy and the production of transgenic non-human animals the chimeric virus offers the advantages of high transduction efficiency, high viral titer, and the ability to have a producer cell which is from the same source as the target cell allowing for the production of autologous secondary viruses which evade the immune response. The chimeric virus is exemplified by an adenovirus which contains a retroviral vector containing a heterologous protein/transgene. Other chimeric viruses are adenovirus-togavirus chimera such as adenovirus-Semiliki Forest virus or adenovirus-Sindbis virus.