

Division of Acute Care, Rehabilitation Research, and Disability Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop F-41, Atlanta, Georgia 30341-3724, telephone (770) 488-4031.

Please refer to Announcement Number 637 when requesting information and submitting an application.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report, Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

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Dated: June 11, 1996.

Joseph R. Carter.

Acting Associate Director for Management and Operations Centers for Disease Control and Prevention (CDC).

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[Announcement 622]

Improving Effectiveness of Tuberculosis Prevention and Control Programs in Developing Countries

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for a grant to provide education, and technical assistance to improve the quality, efficiency, and effectiveness of programs for the prevention and control of tuberculosis (TB) in the developing countries of Central America (Mexico) and Southeast Asia (Vietnam and the Philippines), whose TB situation is of strategic interest to the United States.

CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (To order a copy of "Healthy

People 2000," see the section **WHERE TO OBTAIN ADDITIONAL INFORMATION.**)

Authority

This program is authorized under Section 317E of the Public Health Service Act (42 U.S.C. 247b-6) as amended.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicant

Applications may be submitted by public and private, nonprofit and for-profit organizations and governments and their agencies. Thus, universities, and colleges; and research institutions, hospitals, other public and private organizations, State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply. Applicants must be able to:

1. Demonstrate that their membership is comprised of a wide variety of members from governmental and non-governmental organizations, and individual members that can ensure the success of the activities specified under this program announcement;

2. Document a membership of at least 1,000 persons, including members from each country whose TB situation is of strategic interest to the United States, i.e., Mexico, Vietnam and the Philippines; and

3. Demonstrate experience in providing ongoing technical assistance and practical training for TB programs in a number of countries in the developing world.

Availability of Funds

Approximately \$100,000 is available in FY 1996 to fund one award. The award is anticipated to begin on or about September 1, 1996, for a 12-month budget period within a three-year project period. The funding estimate is subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Purpose

The purpose of this grant is to support and maintain collaborative relationships with organizations to provide TB education, technical assistance and other TB information to TB program managers and non-governmental organizations in developing countries. By providing TB education, information and technical assistance, the management of TB control programs in developing countries will be improved and the global control effort will be enhanced as well as providing additional potential impact on the TB problem in the U.S.

Program Requirements

1. Identify and assess the TB-related public health infrastructure, TB informational needs, and training needs of health care providers and TB control program personnel in developing countries contributing to the U.S. immigrant population, and especially in Mexico, Vietnam, and the Philippines.

2. Facilitate the incorporation of epidemiologic principles in TB national prevention and control programs and expedite the dissemination of epidemiologic findings in order to improve these programs.

3. Encourage collaboration between TB control programs in the United States that have a high prevalence of TB among the foreign born and developing countries in their TB control efforts.

4. Identify and propose project activities in response to findings in 1 through 3 above. These activities may include training courses, support of regional and international meetings designed to improve information transfer on a regional or international basis, and epidemiologic studies that can be used to improve the diagnosis and treatment of TB and improve TB control in developing countries contributing to the U.S. immigrant population, and especially in Mexico, Vietnam, and the Philippines.

Evaluation Criteria

The application will be reviewed and evaluated according to the following criteria. (100 total points maximum)

1. Extent to which the applicant understands the requirements, problems, objectives, complexities, and interactions required of this project (10 Points);

2. Degree to which the proposed epidemiologic studies are realistic and relevant to the purpose of this project (10 Points);

3. Degree to which the proposed programmatic plans are clearly stated, realistic, time phased, and related to the purpose of this project (20 Points);

4. Adequacy of the plans for administering the project. In addition, the degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. Specifically the following items will be addressed (30 Points):

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The appropriateness of the proposed justification when representation is limited or absent.

c. Whether the design of the study is adequate to measure differences when warranted.

d. Whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

5. Extent to which the professional personnel involved proposed to be involved in this project are qualified, including evidence of past achievements appropriate to this project. (30 points)

6. Other—Not scored.

Budget

Consideration will be given to the extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds.

Human Subjects

Procedures adequate for the protection of human subjects must be documented: (1) Protections appear adequate and no comments or concerns are raised, or (2) protections appear adequate, but comments are made regarding the protocol, or (3) protections appear inadequate and the Objective Review Group (ORG) has concerns related to human subjects; or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate resulting in unacceptability of the entire application.

Executive Order 12372

This program is not subject to the Executive Order 12372 review.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.947, TB Demonstration, Research, Public and Professional Education Projects.

Other Requirements

Confidentiality: Applicants must have in place systems to ensure the confidentiality of all patient records.

Human Subjects: The applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurances must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of the IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Women, Racial and Ethnic Minorities: It is the policy of the CDC to ensure that women and racial and ethnic groups will be included in CDC-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947–47951 (a copy is included in the application kit).

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (OMB Number 0937–0189) must be submitted to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers

for Disease Control and Prevention (CDC), 255 East Paces Ferry Road NE., Room 300, Mailstop E–15, Atlanta, GA 30305, on or before July 29, 1996.

1. **Deadline:** Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date, or

(b) Sent on or before the deadline date and received in time for submission to the objective review committee. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. **Late Applications:** Applications that do not meet the criteria in 1.(a) or 1.(b) are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

Questions on application procedures and the application package, and business management technical assistance may be obtained from Juanita Dangerfield, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–15, Atlanta, GA 30305, telephone (404) 842–6577, fax: (404) 842–6513, or Internet address: jdd2@opspgo1.em.cdc.gov.

Programmatic technical assistance may be obtained from: Harry Stern, Division of Tuberculosis Elimination, National Center for STD, HIV, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E–10, Atlanta, GA 30333, telephone (404) 639–8120.

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both regular and overnight mail deliveries. Contacting PGO employees during this time frame may also be hindered due to the possible telephone disruptions.

To the extent authorized, please consider the use of voice mail, e-mail, and facsimile transmissions to the maximum extent practicable. Please do not fax lengthy documents, or grant applications.

This announcement will be available on one of two Internet sites on the publication date: CDC's home page at <http://www.cdc.gov>, or at the Government Printing Office home page (including free access to the Federal Register) at <http://www.access.gpo.gov>.

Dated: June 11, 1996.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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National Institutes of Health

Licensing Opportunity and/or Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of Novel Heparin-Binding Peptides

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

ACTION: Notice.

SUMMARY: The National Institutes of Health is seeking licensees and/or CRADA partners for the further development, evaluation, and commercialization of novel heparin-binding peptides. The inventions claimed in the patent applications referenced below are available for either exclusive or non-exclusive licensing (in accordance with 35 U.S.C. 207 and 37 CFR Part 404) and/or further development under a CRADA for clinical and research applications described below in Supplementary Information.

Heparin- and Sulfatide-Binding Peptides From the Type I Repeats of Human Thrombospondin and Conjugates Thereof

DD Roberts, PJ Browning, J Bryant, JK Inman, HC Krutzsch, N Guo (NCI)

Serial No. 08/487,568, filed 07 Jun 95, which is a CIP of

Serial No. 08/215,085, filed 21 Mar 94, which is a CIP of

Serial No. 07/801,812, which issued as U.S. Patent No. 5,357,041 on 18 Oct 94.

To expedite the research, development, and commercialization of these compounds, the National Institutes of Health is seeking a CRADA with a pharmaceutical or biotechnology company in accordance with the regulations governing the transfer of Government-developed agents. Any proposal to use or develop these compounds will be considered.

ADDRESSES: CRADA proposals and questions about this opportunity should be addressed to: Dr. Gary D. Colby, Office of Technology Development, National Cancer Institute, Executive Plaza South, Suite 450, 6120 Executive Boulevard MSC 7182, Bethesda, MD 20892-7182; telephone: 301/496-0477; fax: 301/402-2117.

Licensing proposals and questions about this opportunity should be addressed to: Ms. Carol Lavrich, 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. 287; fax: 301/402-0220.

Information about the patent applications and pertinent information not yet publicly described can be obtained under 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. Respondees interested in submitting a CRADA proposal should be aware that it may be necessary to secure a license to the above patent rights in order to commercialize products arising from a CRADA.

DATES: There is no deadline by which license applications must be received. CRADA proposals must be received on or before September 16, 1996.

SUPPLEMENTARY INFORMATION: These inventions identify a family of related peptides, peptide analogs, and peptidomimetics useful for blocking or modifying the biological activities of heparin, sulfatides, fibronectin, fibroblast growth factor and transforming growth factor- β (TGF β) Among the activities exhibited by compounds within this family of agents are:

- Inhibition of tumor cell growth, including inhibition of breast tumor growth in a mouse xenograft model;
- Inhibition of Kaposi's Sarcoma (SK) cell proliferation and migration *in vitro* and KS-like lesion formation *in vivo*;
- Inhibition of endothelial and breast carcinoma cell proliferation, adhesion, and motility *in vitro*;

- Inhibition of angiogenesis *in vivo*;
- Specific, high affinity binding to heparin and related sulfated glycoconjugates, including preventing interaction with adhesion molecules, growth factors, cells, and heparin-dependent enzymes; and
- Activation of latent TGF β .

The compounds within this family of agents are based upon functional sequences from the three type I repeats of human endothelial cell thrombospondin. The inventions identify particular peptides, analogs, and peptidomimetics that have particularly advantageous properties such as increased physiological stability, enhanced activity, lack of electrostatic charge, and increased solubility. The inventions also describe unique approaches to constructing water-soluble conjugates which exhibit a number of interesting and useful biological activities.

It is expected that the high potency of these agents will lower the effective dose needed, and, subsequently, will reduce the immunological response against the peptides and the risks of toxicity. Among the diseases for which these agents may prove to be particularly useful therapeutic agents are:

- Kaposi's sarcoma
- Breast carcinoma
- Melanoma
- Other epithelial cancers
- Other diseases involving abnormal vascular proliferation

The inventors of these agents seek collaborators for their ongoing research and development efforts. Two research projects for which collaborators are particularly sought involve investigation of means of controlling angiogenesis and investigation of means for modulating the activity of TGF β , particularly to control fibrosis, using the agents described above.

Thrombospondin has been identified as an anti-angiogenic factor in human epithelial tissue. Certain agents described above have shown particular utility for inhibition of pathological angiogenesis *in vivo*. These agents have been engineered to decrease both proteolytic degradation and the rapidity of their clearance from the bloodstream and to increase their biological activity. These agents have been shown to influence tumor cell adhesion and growth *in vitro* and *in vivo*. Other peptides have been shown to inhibit tumorigenesis and metastasis *in vivo*. Further development of agents, and their application in therapeutic capacities, is planned.

The antiproliferative activities of certain agents upon epithelial and breast