Selection Criteria

In addition to evidence of the ability to fulfill the roles described above, proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following:

(1) Data on the in-vitro anti-HIV activity of the agent;

(2) Animal, human, and in-vitro data on the safety of the agent when applied to mucosal surfaces;

(3) Data on the effects of the agent on rectal mucosa (if available); and

(4) Data on the in-vitro activity of the agent against other sexually transmitted organisms.

Dated: June 22, 2001.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention.

[FR Doc. 01–16243 Filed 6–27–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Opportunity To Collaborate in the Evaluation of Topical Microbicides To Reduce Heterosexual Transmission of Human Immunodeficiency Virus (HIV)

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Opportunities for collaboration for evaluation of topical microbicides.

The Centers for Disease Control and Prevention (CDC), National Center for HIV, STD, and TB Prevention (NCHSTP), Division of HIV/AIDS Prevention-Surveillance and Epidemiology (DHAP–SE), Epidemiology Branch (EpiBr), has an opportunity for collaboration to evaluate the safety and preliminary efficacy of topical microbicides designed for vaginal application to reduce HIV transmission. These evaluations will include in-vitro assays, macaque studies, and phase I/phase II trials in heterosexual women and men.

SUMMARY: The Division of HIV/AIDS Prevention-Surveillance and Epidemiology (DHAP–SE) of the National Center of HIV, STD, and TB Prevention (NCHSTP) at the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (DHHS) seeks one or more pharmaceutical, biotechnological, or other companies who hold a proprietary position on microbicides that are ready for phase I/phase II trials. The selected company and CDC will execute an ''Agreement'' to evaluate the company's microbicides for safety and preliminary efficacy of topical microbicides designed for vaginal application to reduce HIV transmission.

These evaluations will include in-vitro assays, macaque studies, and phase I/phase II trials in heterosexual women and men. Each collaboration would have an expected duration of two (2) to five (5) years. The goals of the collaboration include the timely development of data to further the identification and commercialization of effective topical microbicides and the rapid publication of research findings to increase the number of HIV prevention technologies proven effective and available for use.

Confidential proposals, preferably 10 pages or less (excluding appendices), are solicited from companies with patented or licensed agents which have undergone sufficient preclinical testing to be either (1) currently under an IND application approved by the Food and Drug Administration (FDA) or (2) prepared to submit an IND application to the FDA by December 31, 2001.

DATES: Formal proposals must be submitted no later than July 30, 2001.

ADDRESSES: Formal proposals should be submitted to Jeff Efird, MPA, Epidemiology Branch, Division of HIV/AIDS Prevention—Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–6136, (office) 404–639–6130; Fax: 404–639–6127; e-mail: *JLE1@cdc.gov.* Scientific questions should be addressed to Dawn K. Smith, MD., Epidemiology Branch, Division of HIV/AIDS Prevention—Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–6165, (office) 404–639–6146; Fax: 404–639–6127; e-mail: *Dsmith1@cdc.gov.* Inquiries directed to ''Agreement'' documents related to participation in this opportunity should be addressed to Thomas E. O'Toole, MPH, Deputy Director, Technology Transfer Office, CDC, 1600 Clifton Road, Mailstop E–67, Atlanta, GA 30333; Phone: (direct) 404–639–6270, (office) 404–639–6270; Fax: 404–639–6266; e-mail: *TEO1@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Technology Available

One mission of the Epidemiology Branch of DHAP–SE/NCHSTP is to develop and evaluate biomedical interventions to reduce HIV transmission. To this end, the EpiBr is establishing contracts to conduct phase I and phase II trials of topical microbicides. EpiBr also funds research in the Division of AIDS, STD, and TB Laboratory Research (DASTLR) of the National Center for Infectious Diseases (NCID) at CDC and with external laboratories to conduct macaque studies and in-vitro studies in support of human microbicide trials. The goal of these efforts is to provide scientific and technical expertise and key resources for the evaluation of topical microbicides through late preclinical, phase I, phase II, and proof-of-concept clinical trials.

Technology Sought

EpiBr now seeks potential collaborators having licensed or patented agents for use as vaginal microbicides which:

(1) Have laboratory or animal model evidence of anti-HIV activity;

(2) Have been formulated for vaginal application;

(3) Are not entering phase III clinical trial in the next 12 months;

(4) Have an IND and are currently in phase I clinical trial or have not yet submitted an IND application but have sufficient preclinical data to do so by December 31, 2001; and

(5) Have manufacturing arrangements for production of clinical trial-grade product (an applicator if necessary) under Good Manufacturing Process (c-GMP) standards.

NCHSTP and Collaborator Responsibilities

The NCHSTP anticipates that its role may include, but not be limited to, the following:

(1) Providing intellectual, scientific, and technical expertise and experience to the research project;

(2) Planning and conducting preclinical (in-vitro and in-vivo) research studies of the agent and interpreting results;

(3) Publishing research results;

(4) Depending on the results of these preclinical investigations, NCHSTP may elect to conduct additional research with macaques to evaluate safety and/or efficacy proof-of-concept; and

(5) Depending on the results of preclinical and/or macaque studies and FDA approval, NCHSTP may elect to conduct phase I/II clinical trials of the agent.

The NCHSTP anticipates that the role of the successful collaborator(s) will include the following:

(1) Providing intellectual, scientific, and technical expertise and experience to the research project;

(2) Participating in the planning of research studies, interpretation of

research results and, as appropriate, joint publication of conclusions;

(3) Providing NCHSTP access to necessary proprietary technology and/or data in support of the research activities; and

(4) Providing NCHSTP clinical grade (c-GMP) agent for use in preclinical and clinical studies covered in this collaboration.

Other contributions may be necessary for particular proposals.

Selection Criteria

In addition to evidence of the ability to fulfill the roles described above, proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following:

(1) Data on the in-vitro anti-HIV activity of the agent;

(2) Animal and other data on the safety of the agent when applied to mucosal surfaces;

(3) Data on the effects of the agent on vaginal commensal microbial organisms; and

(4) Data on the in-vitro activity of the agent against other sexually transmitted organisms.

Dated: June 22, 2001.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention.

[FR Doc. 01–16244 Filed 6–27–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Government-Owned Inventions; Availability for Licensing

AGENCY: Centers for Disease Control and Prevention, Technology Transfer Office, Department of Health and Human Services

ACTION: Notice.

The inventions named in this notice are owned by agencies of the United States Government and are available for licensing in the United States (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 copies of the U.S. patent applications listed below, may be obtained by writing to Thomas E. O'Toole, M.P.H., Deputy Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Mailstop E–67, 1600 Clifton Rd., Atlanta, GA 30333, telephone (404) 498–0170, facsimile (404) 498–0095, and e-mail tto@cdc.gov. Please note that a signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

Apparatus for Applying Chemicals to Rodents

This invention comprises a method of controlling Lyme disease by preventing the maturation of deer ticks on white-footed mice by exposing the mice to insecticides as they enter food-baited boxes. Other tick- and flea-borne diseases can also be controlled by this method.

Inventors: Gary O. Maupin *et al.* U.S. Patent Application SN: 09/595,034 (CDC Ref. #: I–031–00).

Control of Arthropod Vectors of Parasitic Diseases

This invention comprises a method of controlling Lyme disease by preventing the maturation of deer ticks on white-footed mice by exposing the mice to insecticides as they enter food-baited boxes. Other tick- and flea-borne diseases can also be controlled by this method.

Inventors: Gary O. Maupin *et al.* U.S. Patent Application SN: 09/595,035 (CDC Ref. #: I–032–00).

Control of Arthropods in Rodents

This invention comprises a method of controlling Lyme disease by preventing the maturation of deer ticks on white-footed mice by exposing the mice to insecticides as they enter food-baited boxes. Other tick- and flea-borne diseases can also be controlled by this method.

Inventors: Gary O. Maupin *et al.* U.S. Patent Application SN: 09/595,177 (CDC Ref. #: I–041–00).

Method for Monitoring Local Reaction Associated With Injections

A simple and inexpensive method to give patients a guideline for determining the severity of an adverse reaction that may occur at the site of injection. Patients can be instructed to notify health care providers if an inflammatory response spreads beyond a measured distance from the location of injection.

Inventor: Laurie Kamimoto, U.S. Patent Application SN: 60/238,691 (CDC Ref. #: I–036–00).

Auscultory Training System

This invention provides for the precise reproduction of recorded sounds. Under ordinary conditions, a sound signal is distorted by the amplifier, speakers, and the surroundings. This invention modifies the signal delivered to the speaker in such a way as to precisely reproduce the signal as it was originally recorded. The graphical user-interface allows for the easy selection and playback of individual components of a larger sound recording. This invention could have applications as a diagnostic screening tool, as a telemedicine tool, and as a teaching tool to instruct the user on the various body sounds, such as lung, bowel, or heart sounds.

Inventors: Walter McKinney *et al.* U.S. Patent Application SN: To be assigned, filed 4.30.2001. (CDC Ref. #: I–037–00).

Peptide Vaccines Against Group A Streptococci

The invention is a vaccine comprised of three synthetic peptides of 20–25 amino acids in length from different M proteins. The synthetic peptides can be recognized by M type-specific antibodies and are capable of eliciting functional opsonic antibodies in mice. The vaccine may have the potential to eliminate over 85% of Group A Streptococci infections and reduce by 85% the nasopharyngeal reservoir of Group A Streptococci in the United States.

Inventors: Bernard Beall *et al.* U.S. Patent Application SN: To be assigned, filed 5.18.2001. (CDC Ref. #: I–039–00)

DNA Synthesis by the Cooperative Action of DNA Polymerase and Nuclease

Confirmation of a diagnosis of an infectious agent usually depends upon the detection of the causative agent or its signature effect on the immune system. Nucleic acid detection methods offer the greatest sensitivity but depend upon specific hybridization of a primer or a probe, thus they can only be used to detect nucleic acids. This invention comprises a novel method of diagnostic detection which retains the sensitivity of nucleic acid based amplification methods while allowing detection of non-nucleic acid targets such as antibodies, surface proteins, or other antigenic components. Thus, no specific sequence information need be known about the potential target.

Inventors: Yuri Khudyakov, U.S. Patent Application SN: (CDC Ref. #: I–043–00)