

must be submitted to the NCI on or before December 10, 1999. Guidelines for preparing final CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest.

#### SUPPLEMENTARY INFORMATION:

##### Technology Available

DHHS scientists within the LDDR, NCI have discovered a novel class of compounds that may have diverse uses in therapy of prophylaxis, or other medical uses, that require inhibition of pathophysiological or physiological processes mediated by vacuolar-type (H+)-ATPases (V-ATPases). Details are in U.S. Patent Application Serial No. 60/122,953, available under an appropriate Confidential Disclosure Agreement.

##### Technology Sought

Accordingly, DHHS now seeks collaborative arrangements for the joint elucidation, evaluation and development of novel compounds and methods to selectively inhibit physiological and/or disease processes that are mediated, at least in part, through specific isoform(s) of V-ATPases. For collaboration with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide for equitable distribution of intellectual property rights developed under the CRADA. CRADA aims will include rapid publication of research results as well as full and timely exploitation of any commercial opportunities.

##### NCI and Collaborator Responsibilities

The role of the LDDR, NCI in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.
2. Providing the Collaborator with pertinent available compounds for investigation/evaluation.
3. Planning research studies and interpreting research results.
4. Publishing research results.

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

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.
2. Planning research studies and interpreting research results.
3. Providing technical expertise and/or financial support for CRADA-related research as outlined in the CRADA Research Plan.
4. 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 on-going research and development.
2. Expertise and experience in the following areas: preclinical research and drug development of selective vacuolar-type ATPase-inhibitory compounds; ability to perform appropriate chemical synthetic efforts to support V-ATPase-directed structure/activity (SAR) studies, lead-optimization, drug candidate selection and development; performance of *in vitro* and/or *in vivo* assays of V-ATPase inhibition employing distinctive V-ATPases from diverse human and other mammalian tissues and cells.
3. The demonstration of adequate resources to perform the research, development and commercialization 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.
4. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.
5. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of technology.
6. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.
7. 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.
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. 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 non-exclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: October 29, 1999.

**Kathleen Sybert,**

*Chief, Technology Development & Commercialization Branch, National Cancer Institute, National Institutes of Health.*  
[FR Doc. 99-29367 Filed 11-9-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood 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 a meeting of the Board of Scientific Counselors, NHLBI.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Heart, Lung, and Blood Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NHLBI.

*Date:* December 9-10, 1999.

*Time:* 8 am to 5 pm.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, 9000 Rockville Pike, Building 10, Room 7S235, Bethesda, MD 20892.

*Contact Person:* Elizabeth G. Nabel, Director of Clinical Research Programs, National Heart, Lung, and Blood Institute, Division of Intramural Research, Building 10, Room 8C103, MSC 1754, Bethesda, MD 20892, 301/496-1518.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 3, 1999.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-29378 Filed 11-9-99; 8:45 am]

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