can take to an attenuated HPIV vaccine. Certain candidate human-bovine chimeric PIV vaccine strains are not available for licensing.

Production of Attenuated Negative Stranded RNA Virus Vaccines From Cloned Nucleotide Sequences

Inventors: Brian R. Murphy, Peter L. Collins, Anna P. Durbin, and Mario H. Skiadopoulos.

Serial Number: 60/129,006.

Filling Date: April 13, 1999.

Negative stranded RNA viruses (the Mononegavirales) include RSV, PIV, measles, mumps and rabies as human pathogens. Recombinant production of live attenuated virus strains as vaccine candidates has involved, for each virus, identifying attenuating mutations and producing recombinant virus strains with different combinations of mutations in a hunt for the right balance of attention and immunogenicity. This invention dramatically increases the number of mutations available. The inventors have shown that attenuating mutations in one negative stranded RNA virus can be ''transferred'' to homologous locations in other negative stranded RNA viruses, resulting in a transfer of the attenuation phenotype. Now, many of the attenuating mutations known for RSV or PIV can be transferred between each of these viruses, or into the other less studied members of this family. Also mutations identified in other paramyxoviruses, such as measles virus, can be transferred to RSV and PIV. Such transformations have been performed and show that this general approach works. Certain candidates RSV and PIV vaccine strains are not available for licensing.

The CRADA will employ attenuated human-animal chimeric RSV and PIV strains developed in LID using recombinant DNA methodologies to (1) identify and characterize the mutations responsible for attenuation, (2) engineer viral strains suitably attenuated for use as human vaccines, and (3) evaluate the attenuated viruses as live vaccines in animals and humans.

The LID has extensive experience in evaluating the safety, antigenicity, immunogenicity and efficacy of various human viral pathogens and vaccines thereof both in experimental animals and human volunteers. The Collaborator in this endeavor is expected to commit several scientists off-site to support the activities defined by the CRADA Research Plan.

These scientists, in collaboration with investigators in the LID, would coordinate the production and release testing of the candidate vaccines, generate monoclonal antibodies needed for manufacture of clinical lots and for their clinical evaluation, and use molecular virologic techniques to generate attenuating mutations suitable for use in live vaccine candidates. In addition, it is expected that the Collaborator will provide funds to supplement LID's research budget for the project and would make a major funding commitment to support the safety, immunogenicity and efficacy studies for candidate vaccines developed under the CRADA.

The capability statement must address, with specificity, each of the following selection criteria: (1) The technical expertise of the Collaborator's Principal Investigator and laboratory group in molecular virology, (2) Ability of Collaborator to manufacture experimental vaccine lots for parental administration under Good Manufacturing Practices (GMP) conditions, and (3) Ability to provide adequate and sustained funding to support the requisite vaccine safety and efficacy studies.

Dated: October 26, 1999.

Mark Rohrbaugh,

Director, Office of Technology Development, NIAID.

Dated: October 29, 1999.

Jack Spiegel,

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

[FR Doc. 99–29368 Filed 11–9–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Drug Research and Development of a Novel Vacuolar-Type (H+)-ATPase-Inhibitory Compound Class

AGENCY: National Cancer Institute, National Institute of Health, PHS, DHHS.

ACTION: Notice of opportunity for cooperative research and development (CRADA).

An opportunity is available for a Cooperative Research and Development Agreement (CRADA) for the purpose of collaborating with the NCI intramural Laboratory of Drug Discovery Research & Development (LDDRD) on further research and development of U.S. government-owned technology encompassed within U.S. Patent Application Serial No. 60/122,953, entitled ''Novel Vacuolar-Type (H+)-ATPase-Inhibitory Compounds and Compositions, and Uses Thereof.''

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks a Cooperative Research and Development Agreement ((CRADA) with a pharmaceutical or biotechnology company to develop new drugs, therapeutic and/or preventative methods based on selective inhibition of vacuolar-type (H+) ATPases. The CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, methods of treatment or prevention that may result from the research. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA and which are subject of the CRADA Research Plan, and can apply for background licenses to the existing patent described above, subject to any pre-existing licenses already issued for other fields of use.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Bjarne Gabrielsen, Technology Development & Commercialization Branch, National Cancer Institute-Frederick Cancer Research & Development Center, Fairview Center, Room 502, Frederick, MD 21701 (phone: 301–846–5465, fax: 301–846–6820).

Scientific inquiries should be directed to Dr. Michael R. Boyd, Chief Laboratory of Drug Discovery Research & Development, National Cancer Institute-Frederick Cancer Research & Development Center, Bldg. 1052, Rm 121, Frederick, MD 21702–1201 (phone: 301–846–5391; fax: 301–846–6919; e-mail boyd@dtpax2.ncifcrf.gov).

EFFECTIVE DATE: Inquiries regarding CRADA proposals and scientific matters may be forwarded at any time. Confidential preliminary CRADA proposals, preferably two pages or less,

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 LDDRD, 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 phyiological 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 LDDRD, 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]

BILLING CODE 4140–01–M

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]

BILLING CODE 4140–01–M