

or call non toll-free at (301) 435-2932. You may also e-mail your request to dr3p@nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: February 1, 2001.

Anne Thomas,

Assoc. Director, Office of Communications and Public Liaison, National Institutes of Health.

[FR Doc. 01-3607 Filed 2-12-01; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): Opportunity for Cooperative Research and Development Agreements (CRADAs) to Develop Monoclonal Antibodies and/or Other Reagents and Products for Use in Identifying the Dombrock Blood Group Carrier Molecule Aimed at Improving Blood Typing Practices Through Molecular Means

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

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) is seeking Licensee(s) and/or proposals in the form of capability statements from potential collaborators for a Cooperative Research and Development Agreement (CRADA) to develop monoclonal antibodies and/or other reagents and products for use in identifying the Dombrock blood group carrier molecule. The U.S. government-owned technology is encompassed within U.S. Provisional Patent Application Serial No. 60/235,162, entitled "Identification of The Dombrock Blood Group Glycoprotein as a Polymorphic Member of The ADP-Ribosyltransferase Gene Family".

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 Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) 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 monoclonal antibodies and/or other reagents for use in identifying the Dombrock blood group carrier molecule. The goals of the CRADA include the rapid publication of research results and timely commercialization of products or methods that may result from the research.

The potential Collaborator(s) capability statement should provide proof of expertise in blood typing practices through molecular means along with a brief commercialization plan. The NIH also will consider proposals from Collaborators with demonstrated expertise in developing kits designed to identify blood group antibodies in recipients of transfused blood or blood products.

DATES: Only written CRADA capability statements received by the NIDDK on or before March 30, 2001 will be considered during the initial design phase; confidential information must be clearly labeled. Potential Collaborators may be invited to meet with the Selection Committee at the Collaborator's expense to provide additional information. The Institute may issue an additional notice of CRADA opportunity during the design phase.

FOR FURTHER INFORMATION CONTACT:

Capability statements should be submitted to Dr. Michael W. Edwards, Office of Technology Development, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, BSA Building, Suite 350 MSC 2690, 9190 Rockville Pike, Bethesda, MD 20814-3800; Tel: 301/496-7778, Fax: 301/402-0535; Email: mels@nih.gov.

SUPPLEMENTARY INFORMATION: A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. It is not a grant, and is not a contract for the procurement of goods/services. The NIDDK is prohibited from transferring funds to a CRADA collaborator. Under a CRADA, NIDDK can contribute facilities, staff, materials, and expertise to the effort. The collaborator typically contributes facilities, staff, materials, expertise, and funding to the collaboration. The CRADA collaborator receives an exclusive option to negotiate an exclusive or non-exclusive license to Government intellectual property rights arising under the CRADA in a pre-determined field of use and may qualify

as a co-inventor of new technology developed under the CRADA.

Identification of the 25 known human blood group molecules is of fundamental importance for the fields of erythroid cell biology and transfusion medicine. The molecular description of the "Dombrock" blood group system has been determined. A candidate gene was identified by in silico analyses of approximately 5000 expressed sequence tags (ESTs) from terminally differentiating human erythroid cells. Transfection experiments demonstrated specific binding of anti-Dombrock and confirmed glycosylphosphatidylinositol membrane attachment.

Currently, reagents may not be available to readily type all blood using serology. The information derived by this invention of the Dombrock blood group carrier gene can be used to type the human blood supply. The public health need is to improve the blood typing practices through molecular means and thereby prevent clinical problems associated with improperly cross-matched blood.

Capability Statements

A Selection Committee will utilize the information provided in the "Collaborator Capability Statements" received in response to this announcement to help in its deliberations. It is the intention of the NIDDK that all qualified Collaborators have the opportunity to provide information to the Selection Committee through their capability statements. The Capability Statement should not exceed 10 pages and should address the following selection criteria:

(1) The statement should provide specific details of the method to be utilized in the development of the monoclonal antibody to the Dombrock molecule.

(2) The statement should include a detailed plan demonstrating the ability to provide sufficient quantities of the agent in a timely manner for the duration of the study.

(3) The statement may include outline outcome measures of interest to the Collaborator. The specifics of the proposed outcome measures and the proposed support should include but not be limited to the following: monoclonal development expertise, specific funding commitment to support the advancement of scientific research, personnel services, facilities, equipment, or other resources that would contribute to the conduct of the commercial development.

(4) The statement must address willingness to promptly publish research results and ability to be bound

by PHS intellectual property policies (see CRADA: <http://ott.od.nih.gov/newpages/crada.pdf>).

Licensing Information

This technology was previously advertised in the December 26, 2000 issue of the **Federal Register** as a licensing opportunity [65 FR 81532]. Briefly, the gene and its polymorphisms that result in the Dombrock blood group antigenicity, for the first time, provide a route for reliable blood typing. Products aimed at improving blood typing practices through molecular means, thereby preventing mismatched blood transfusions, can also be developed with this technology. For the sake of completeness, the licensing contact is provided here: John Rambosek; 301/496-7056, ext. 270; fax: 301/402-0220; e-mail: rambosej@od.nih.gov.

Dated: February 5, 2001.

Jack Spiegel,

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

[FR Doc. 01-3603 Filed 2-12-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

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 writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Potential of Antineoplastic Agents Using Sigma 2 Ligands

Keith W. Crawford, Wayne D. Bowen (NIDDK)
DHHS Reference No. E-165-99/0 filed 11 May 2000

Licensing Contact: Catherine Joyce; 301/496-7735 ext. 244; e-mail: joycec@od.nih.gov.

The inventors have developed a therapeutic method of treating cancer through the administration of a sigma-2 receptor ligand, such as CB-184, in combination with the anti-neoplastic drugs, doxorubicin or actinomycin D. The novel combination produces marked tumor cell death at concentrations that produce little or no cytotoxicity when cells are exposed to the drugs alone. The protocol may be effective in treating tumors that are resistant to antineoplastics alone as a result of mutations of the p53 tumor suppressor gene.

Tumor Markers in Ovarian Cancer

Patrice J. Morin, Colleen D. Hough, Cheryl A. Sherman-Baust, Ellen S. Pizer (NIA)
DHHS Reference No. E-138-00/0 filed 03 Apr 2000

Licensing Contact: Catherine Joyce; 301/496-7735 ext. 244; e-mail: joycec@od.nih.gov.

This invention relates generally to the identification of ovarian tumor markers and diagnostic, prognostic and therapeutic methods for their use. The invention is based on the identification of a series of ovarian tumor marker genes that are highly expressed in ovarian epithelial tumor cells and are minimally expressed in normal ovarian epithelial cells.

Imidazoacridones With Anti-Tumor Activity

Cholody et al. (NCI)
DHHS Reference No. E-289-99/0 filed 07 March 2000

Licensing Contact: Girish Barua; 301/496-7735 ext. 263; e-mail: baruag@od.nih.gov.

The present invention relates to novel bifunctional molecules with anti-tumor activity. These agents are composed of an imidazoacridone moiety linked by a nitrogen containing aliphatic chain of various length and rigidity to another aromatic ring system capable of intercalation to DNA.

Previous studies on related symmetrical bis-imidazoacridones revealed that only one planar imidazoacridone moiety intercalates into DNA. The second aromatic moiety which is crucial for biological activity resides in DNA groove, and is believed

to interact with DNA-binding proteins (most likely, transcription factors). It was hypothesized that action of bis-imidazoacridone constitute a new paradigm of how small molecules can interfere with gene transcription.

To enhance the biological activity, the inventors have developed unsymmetrical compounds in which one imidazoacridone system with relatively poor DNA-intercalating properties was replaced with much stronger intercalators, such as 3-chloro-7-methoxyacridine or naphthalimide moieties. These new compounds, especially those containing naphthalimide moiety are extremely cytotoxic against variety of tumor cells in vitro (IC₅₀ at low nanomolar range) and kill tumor cells by inducing apoptosis. In vivo, in nude mice xenografted with human tumors, the compounds significantly inhibited growth of such tumors as colon tumor HCT116 and Colo205 as well pancreatic tumors (lines 6.03 and 10.05 freshly established from a patient).

Dated: February 6, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 01-3604 Filed 2-12-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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