Nelson, M.D., M.P.H., Project Officer, National Cancer Institute, NIH, 6130 Executive Boulevard, EPN 4068, MSC 7365,Bethesda, Maryland 20852–7365, or call non-toll-free number (301) 594–9904, or FAX your request to (301) 480–2087, or E-mail your request, including your address, to *dn83r@nih.gov.*

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

Dated: May 21, 2002.

Reesa L. Nichols,

NCI Project Clearance Liaison.

[FR Doc. 02–13277 Filed 5–24–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Opportunity for Cooperative Research and Development Agreement(s) (CRADAs) and/or License(s) for the Development and Commercialization of *Nitric Oxide-Releasing Drugs and Biomaterials*

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks Licensee(s) and/or Cooperative Research and Development Agreement (CRADA) Collaborator(s) for the development and commercialization of Nitric Oxide (NO)-Releasing Drugs and Biomaterials as embodied in a variety of recent NCI publications, as well as, in the patents and patent applications listed below.

DATES: Confidential CRADA proposal summaries, preferably one page or less, and a signed Confidential Disclosure Agreement (CDA) (*http://ttb.nci.nih.gov/forms.html*) must be submitted to the NCI Technology Transfer Branch (TTB) on or before June 24, 2002, to take full advantage of this opportunity. CRADA proposal summaries submitted thereafter may be considered if a suitable CRADA Collaborator is not selected from among the timely responses. Guidelines for preparing a full CRADA proposal will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest.

Respondees interested in licensing the invention(s) should submit an ''Application for License to Public Health Service Inventions''. The licensing application, model licenses and other information on licensing NIH technologies can be found at *http://ott.od.nih.gov* under Intramural Licensing Program.

ADDRESSES: CRADA information may be obtained by contacting Dr. Charmaine Richman, Technology Transfer Specialist, Technology Transfer Branch, National Cancer Institute, 1003 West Seventh Street, Suite 500, Frederick, Maryland 21701; telephone: 301–846–5465; fax 301–846–6820; e-mail: *richmanc@mail.nih.gov.*

Licensing information and copies of the issued U.S. patents referenced below may be obtained by contacting Dr. Norbert Pontzer, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301–496–7057 ext. 284; fax 301–402–0220; e-mail: *PontzerN@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of patent applications that have not yet issued.

Scientific inquiries may be directed to Dr. Larry Keefer, National Cancer Institute/Center for Cancer Research (CCR) at Frederick, Building 538, Room 205F, Frederick, MD 21702–1201; telephone : 301–846–1467; e-mail: *keefer@ncifcrf.gov.*

SUPPLEMENTARY INFORMATION: NIH scientists are developing a variety of novel techniques for delivering nitric oxide (NO) to specific organs and cell types for therapeutic benefit. Methods for targeting lung, liver, and other tissues have been introduced to the literature, as have NO-releasing proteins and insoluble polymers. The compounds and drug delivery strategies developed thus far have shown promising activities that have been demonstrated in relevant experimental animal models. These include inhibition of thrombosis, treatment of vasospasm, relief of respiratory distress, protection against toxic liver injury, radiosensitization of hypoxic tumors, correction of genitourinary tract dysfunction, antimicrobial effects, protection against ischemia-reperfusion injury and whole-body radiation, and preservation of organ transplants. Inventions described in the patents are available for either exclusive or non-exclusive licensing in accordance with 35 U.S.C. 207 and 37 CFR 404.

A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into with NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of April 10, 1987, as amended. A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. It is not a grant, and it is not a contract for procurement of goods/services. The NCI is prohibited from transferring funds to a CRADA collaborator. Under a CRADA, NCI can contribute facilities, staff, materials, and expertise. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADA. CRADA applicants should be aware that a license to the above-mentioned patent rights may be necessary in order to commercialize products arising from a CRADA. The expected duration of the CRADA(s) would be for up to five (5) years. The goals of CRADAs include rapid publication of research results and timely commercialization of products, diagnostics, and treatments that result from the research.

Nitric Oxide Patents

Patent Status: Compositions and uses covered in:

1. Keefer, L.K., Wink, D.A., Dunams, T.M., and Hrabie, J.A.: Stabilized nitric oxide-primary amine complexes useful as cardiovascular agents. U.S. Patent 4,954,526, September 4, 1990.
2. Keefer, L.K., Wink, D.A., Dunams, T.M., and Hrabie, J.A.: Anti-hypertensive compositions of secondary amine-nitric oxide adducts and use thereof. U.S. Patent 5,039,705, August 13, 1991.
3. Keefer, L.K., and Hrabie, J.A.: Complexes of nitric oxides with polyamines. U.S. Patent 5,155,137, October 13, 1992.
4. Diodati, J.G., and Keefer, L.K.: Therapeutic inhibition of platelet aggregation by nucleophile-nitric oxide complexes and derivatives thereof. U.S. Patent 5,185,376, February 9, 1993.
5. Keefer, L.K., Wink, D.A., Dunams, T.M., and Hrabie, J.A.: Anti-hypertensive compositions of secondary amine-nitric oxide adducts and use thereof. U.S. Patent 5,208,233, May 4, 1993 (continuation in part of U.S. Patent 5,039,705).
6. Keefer, L.K., Wink, D.A., Dunams, T.M., and Hrabie, J.A.: Anti-hypertensive compositions and use thereof. U.S. Patent 5,212,204, May 18, 1993.
7. Keefer, L.K., and Hrabie, J.A.: Complexes of nitric oxide with polyamines. U.S. Patent 5,250,550, October 5, 1993 (continuation in part of U.S. Patent 5,155,137).
8. Keefer, L. K., Dunams, T.M., and Saavedra, J.E.: Oxygen-substituted

derivatives of nucleophile-nitric oxide adducts as nitric oxide donor prodrugs. U.S. Patent 5,366,997, November 22, 1994.

9. Christodoulou, D.D., Wink, D.A., and Keefer, L.K.: Mixed ligand metal complexes of nitric oxide nucleophile adducts useful as cardiovascular agents. U.S. Patent 5,389,675, February 14, 1995.

10. Keefer, L.K., and Hrabie, J.A.: Polymer-bound nitric oxide/nucleophile adduct compositions, pharmaceutical compositions incorporating same and methods of treating biological disorders using same. U.S. Patent 5,405,919, April 11, 1995.

11. Keefer, L.K., Hrabie, J.A., and Saavedra, J.E.: Polymer-bound nitric oxide/nucleophile adduct compositions, pharmaceutical compositions incorporating same and methods of treating biological disorders using same. U.S. Patent 5,525,357, June 11, 1996 (continuation in part of U.S. Patent 5,405,919).

12. Malinski, T., Wink, D.A., Younathan, J., Murray, R.W., Sullivan, M., Meyer, T.J., and Christodoulou, D.D. Nitric oxide sensor. U.S. Patent 5,603,820, February 18, 1997.

13. Saavedra, J.E., Keefer, L.K., Roller, P. P., and Akamatsu, M.: Bipolymer-bound nitric oxide-releasing compositions, pharmaceutical compositions incorporating same and methods of treating biological disorders using same. U.S. Patent 5,632,981, May 27, 1997 (continuation in part of U.S. Patent 5,525,357).

14. Mitchell, J.B., Russo, A., Krishna, M.C., Wink, D.A., and Liebmann, J.E. Use of nitric oxide releasing compounds as hypoxic cell radiation sensitizers. U.S. Patent 5,650,442, July 22, 1997.

15. Keefer, L.K., and Hrabie, J.A.: Implants, prostheses, and stents comprising polymer-bound nitric oxide-nucleophile adducts capable of releasing nitric oxide. U.S. Patent 5,676,963, October 14, 1997.

16. Hrabie, J.A., and Keefer, L.K.: Method of generating nitric oxide gas using nitric oxide complexes. U.S. Patent 5,683,668, November 4, 1997.

17. Smith, D.J., Chakravarthy, D., and Keefer, L.K.: Polysaccharide-bound nitric oxide-nucleophile adducts. U.S. Patent 5,691,423, November 25, 1997 (continuation in part of U.S. Patent 5,405,919).

18. Korthuis, R.J., Kong, L., and Keefer, L.K.: Use of nitric oxide-releasing agents for reducing metastasis risk. U.S. Patent 5,700,830, December 23, 1997.

19. Saavedra, J.E., Keefer, L.K., and Billiar, T.R.: Selective prevention of organ injury in sepsis and shock using selective release of nitric oxide in vulnerable organs. U.S. Patent 5,714,511, February 3, 1998.

20. Keefer, L.K., and Hrabie, J.A.: Polymer-bound nitric oxide/nucleophile adduct compositions, pharmaceutical compositions incorporating same and methods of treating biological disorders using same. U.S. Patent 5,718,892, February 17, 1998 (divisional application of U.S. Patent 5,405,919).

21. Keefer, L.K., Saavedra, J.E., and Hrabie, J.A.: N-Substituted piperazine NONOates. U.S. Patent 5,721,365, February 24, 1998.

22. Keefer, L.K., Wink, D.A., Dunams, T.M., and Hrabie, J.A.: Anti-hypertensive compositions of secondary amine-nitric oxide adducts and use thereof. U.S. Patent 5,731,305, March 24, 1998.

23. Wink, D.A., Mitchell, J.B., Russo, A., Krishna, M.C., Hanbauer, I., Grisham, M.B., and Granger, D.N. Nitric oxide releasing compounds as protective agents in ischemia reperfusion injury. U.S. Patent 5,789,447, August 4, 1998.

24. Mitchell, J.B., Russo, A., Krishna, M.C., Wink, D.A., and Liebmann, J.E. Use of nitric oxide-releasing compounds as hypoxic cell radiation sensitizers. U.S. Patent 5,814,667, September 19, 1998 (divisional application of U.S. Patent 5,650,442).

25. Green, S.J., and Keefer, L.K.: Encapsulated and non-encapsulated nitric oxide generators used as antimicrobial agents. U.S. Patent 5,814,666, September 29, 1998.

26. Saavedra, J.E., and Keefer, L.K.: Selective prevention of organ injury in sepsis and shock using selective release of nitric oxide in vulnerable organs. U.S. Patent 5,814,656, September 29, 1998 (divisional application of U.S. Patent 5,714,511).

27. Keefer, L.K., Saavedra, J.E., Doherty, P.C., Hanamoto, M.S., and Place, V.A.: Use of nitric oxide-releasing agents to treat impotency. U.S. Patent 5,910,316, June 8, 1999 (continuation in part of U.S. Patent 5,525,357).

28. Keefer, L.K., and Hrabie, J.A.: Polymer-bound nitric oxide/nucleophile adduct compositions, pharmaceutical compositions incorporating same and methods of treating biological disorders using same. U.S. Patent 6,110,453, August 29, 2000 (divisional application of U.S. Patent 5,718,892).

29. Saavedra, J.E., Keefer, L.K., Roller, P.P., and Akamatsu, M.: Biopolymer-bound nitric oxide-releasing compositions, pharmaceutical compositions incorporating same and methods of treating biological disorders using same. U.S. Patent 6,200,558, March 13, 2001 (continuation in part of U.S. Patent 5,525,357).

30. Hrabie, J.A., and Keefer, L K.: Nitric oxide-releasing amidine- and enamine-derived diazeniumdiolates, compositions and uses thereof and methods of making same. U.S. Patent 6,232,336, May 15, 2001.

31. Keefer, L.K., Saavedra, J.E., Doherty, P.C., Hanamoto, M.S., Place, V. A.: Use of nitric oxide-releasing agents to treat impotency. U.S. Patent 6,290,981, September 18, 2001.

32. Saavedra, J.E., Srinivasan, A., and Keefer, L.K.: O2–Aryl substituted diazeniumdiolates. U.S. Patent Application 60/026,816, filed September 27, 1996.

33. Saavedra, J.E., Keefer, L.K., and Bogdan, C.: O2–Glycosylated 1-substituted diazen-1-ium-1,2-diolates and O2-substituted 1-[(2-carboxylato)pyrrolidin-1-yl]diazen-1-ium-1,2-diolates. U.S. Patent Application 60/051,696, filed July 3, 1997.

34. Saavedra, J.E., et al.: Nitric oxide-releasing 1-[(2 carboxylato)pyrrolidin-1-yl]diazen-1-ium-1,2,-diolates and composition comprising same. U.S. Patent Application 09/666,668, filed September 20, 2000.

Party Contributions to CRADAs

The role of the National Cancer Institute 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 samples of the subject compounds for pharmacological evaluation.

3. Planning research studies and interpreting research results.

4. Providing support services at NCI/CCR.

5. 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 support for ongoing CRADA-related research in the development of the particular application of nitric oxide-releasing drugs/biomaterials outlined in the Agreement:

a.Financial support to facilitate scientific goals;

b.Technical or financial support for further design of applications.

4. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but are not 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 ongoing research and development.

2. 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.

3. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.

4. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of technology.

5. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.

6. The willingness to cooperate with the NCI 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 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 nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: May 17, 2002.

Kathleen Sybert,

Chief, Technology Transfer Branch, National Cancer Institute, National Institutes of Health.

Dated: May 13, 2002.

Jack Spiegel,

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

[FR Doc. 02–13196 Filed 5–24–02; 8:45 am]

BILLING CODE 4140–01–P

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.

MRP8, A Member of the ABC Transporter Superfamily Highly Expressed in Breast Cancer, and Uses Thereof

Ira Pastan et al. (NCI)
DHHS Reference No. E–225–01/0 12 Jul 2001
Licensing Contact: Richard Rodriguez; 301/496–7056 ext. 287; e-mail: rodrigur@od.nih.gov

MRP8 encodes an ATP-binding cassette transporter protein. Current data shows that it is expressed in a restrictive manner, and that it is highly expressed in breast cancer cells. This expression pattern makes it suitable as a molecular target, and MRP8-specific antibodies could be used to target MRP8-expressing cancer cells. Additionally, the MRP8-protein, immunogenic portions of said protein or nucleic acids encoding the protein, or immunogenic portions of said protein, could be used as immunogens to stimulate or to augment immune responses to MRP8-expressing cancer cells.

The Ovachip: A Clinically Useful cDNA Array for Differential Diagnosis of Ovarian Cancer

Morin et al. (NIA)
DHHS Reference No. E–344–01/0 filed 06 Mar 2002
Licensing Contact: Matthew Kiser; 301/496–7056 ext. 224; kiserm@od.nih.gov

The present invention describes a specialized microarray that exclusively contains genes that are differentially expressed in ovarian cancer. The invention also provides for methods of generating an expression profile of multiple genes that are differentially expressed in ovarian cancer, methods of determining treatment for an ovarian tumor, and methods of identifying clusters of coordinately regulated genes that are differentially expressed in ovarian cancer.

Benefits of this invention include methods of predicting the response of a mammal to an anti-ovarian cancer therapeutic regimen, methods of monitoring cancer progression, methods of determining the efficacy of anti-cancer drugs, and methods of screening candidate anti-ovarian drugs for efficacy. All these applications hinge on the use of these ovarian cancer gene microarrays in generating gene expression profiles under various conditions and comparing them to each other and to standards.

Method of Promoting Engraftment of a Donor Transplant in a Recipient Host

William J. Murphy et al. (NCI)
DHHS Reference No. E–151–01/0 filed 29 Jun 2001
Licensing Contact: Matthew Kiser; 301/496–7056 ext. 224; e-mail: kiserm@od.nih.gov

This invention pertains to a method of using donor natural killer (NK) cells to promote engraftment of a donor transplant in a recipient host, wherein the donor NK cells have been treated ex vivo, such as with an antibody (or antigenically reactive fragment thereof), a major histocompatibility molecule (MHC), a small molecule, a blocker of cell-signaling or an enzyme, such that the ability of the donor NK cells to interact with MHC molecules in the recipient host is compromised.

The method comprises adoptively transferring to the recipient host donor NK cells, which have been treated ex vivo to interfere with the ability of inhibitory receptors on the donor NK cells to interact with MHC molecules in the recipient host, simultaneously with, or sequentially to, in either order, the donor transplant, whereupon the engraftment of the donor transplant in the recipient host is promoted.

The present inventive method has applications in the context of the transplantation of a variety of tissues from the donor to the recipient host. In