QOD × 3 (0.25 mg/kilo) produced complete tumor regressions without death or toxicity. Since the antibody does not react with mouse mesothelin, possible toxicities in mice are due to non-specific (liver) toxicity. NIH/NCI scientists have also administered this aforementioned single chain form to monkeys. SS(Fv)-PE38 reacts just as strongly with monkey mesothelin as it does with human mesothelin, and therefore, one would expect the monkey to be a good predictor of toxicity in humans. At a 0.05 mg/kilo dose level, no toxicity was experienced. A second monkey received 0.5 mg/kilo and showed a transient elevation in liver enzymes and non-specific physical signs (inactivity), but fully recovered.

In the United States, an estimated 15,000 patients die of ovarian cancer each year despite therapy. Although less common, mesotheliomas are known to be resistant to all chemotherapeutic agents. Development of new therapeutic modalities to treat these malignancies is needed.

A Cooperative Research and Development Agreement or CRADA means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer Advancement Act of 1995 to collaborate to improve the properties of the SS(dsFv)-PE38 immunotoxin.

The rule of the NCI in the CRADA may include, but are 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 to create, optimize, test and develop targeted drugs for clinical studies.
3. Planning research studies and interpreting research results.
4. Carrying out research to improve the properties of the SS(dsFv)-PE38 which include, but are not restricted to, increased production yield, decreased side effects, increased cytotoxic activity and better tissue penetration.
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 samples of the subject compounds to create, optimize, test and develop targeted drugs for clinical studies.
4. Providing technical and/or financial support to facilitate scientific goals and for further design of applications of the technology outlined in the agreement.
5. Incorporating the immunotoxin into liposomes or producing other formulations in order to increase the therapeutic efficacy.
6. Providing immunotoxin for laboratory and animal studies.
7. 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 ongoing research and development.
2. The demonstration of adequate resources to perform the research and development 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 and development of this technology, as outlined in the CRADA Collaborator's proposal.
4. The demonstration of expertise in the commercial development and production 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 demonstration of expertise pertinent to the development of models to evaluate and improve the efficacy of the SS (dsFv)-PE38 immunotoxin for the treatment of ovarian cancer and mesotheliomas.
7. The demonstration of expertise in the formulation of drugs into liposomes or other delivery vehicles.
8. The willingness to cooperate with the NCI in the timely publication of research results.
9. 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.
10. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any.

These provisions govern the 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 nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: May 18, 1998.

Jack Spiegel,

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

Dated: May 26, 1998.

Kathleen Sybert,

Acting Director, Technology Development and Commercialization Branch, National Cancer Institute, National Institutes of Health.

[FR Doc. 98–16426 Filed 6–19–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: Novel Antitumor Macrocyclic Lactones, Compositions and Methods of Use

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

ACTION: Notice.

SUMMARY: The National Institutes of Health is seeking licensees for the further development, evaluation and commercialization of materials and methods for novel cancer treatment agents. The invention claimed in DHHS Reference No. E–244–97/0, ''Novel Antitumor Macrocyclic Lactones, Compositions and Methods of Use,'' (Boyd, M. et al.) filed on 29 June 1997 as USSN 60/053,784, is available for licensing (in accordance with 35 USC 207 and 37 CFR Part 404).

ADDRESSES: Questions about the licensing opportunity should be addressed to Girish C. Barua, Ph.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; Telephone: 301/496–7056 ext. 263; Fax: 301/402–0220.

SUPPLEMENTARY INFORMATION: The invention relates to a series of macrocyclic lactones based on compounds isolated from certain marine sponges and tunicates. These compounds have *in vitro* activity against certain human solid tumors, including non-small cell lung cancer, renal cancer and melanoma, all important killers which are resistant to currently used drugs.

Of particular interest is the cell-line activity profile of these lactones, which indicates a novel mechanism of action. Such compounds hold the promise of *in*

vivo activities unlike those seen with current drugs. These lactones thus have the potential for use as therapeutics alone or in combination with existing drugs.

Information about the patent application and pertinent information not yet publicly described can be obtained under a Confidential Disclosure Agreement. Respondees interested in licensing the invention will be required to submit an Application for License to Public Health Service Inventions.

Dated: June 16, 1998.

Jack Spiegel,

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

[FR Doc. 98–16425 Filed 6–19–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDKI GRB–4(02).

Date: July 15–16, 1998.

Time: July 15, 1998, 7:30 pm to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 5 Boston, MA 02114.

Contact Person: William Elzinga, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS–37, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–8895.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 12, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–16430 Filed 6–19–98; 8:45 am]

BILLING CODE 1410–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of person privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB–4(03).

Date: June 30, 1998.

Time: 3:00 pm to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Natcher Building, 45 Center Drive, Room 6AS.25S, MD 20892 (Telephone Conference Call).

Contact Person: William Elzinga, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS–37, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–8895.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 12, 1998.

Laverne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–16431 Filed 6–9–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Multidisciplinary Sciences Special Emphasis Panel, ZRG7 SSS–7(67).

Date: June 22–23, 1998.

Time: 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Houston Baker, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7854, Bethesda, MD 20892–7854, (301) 435–1175.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Multidisciplinary Sciences Special Emphasis Panel, sss–x(6).

Date: June 22, 1998.

Time: 2:00 pm to 3:30 pm.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lee Rosen, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435–1171.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Multidisciplinary Sciences Special Emphasis Panel, ZRG7 SSS–7 (68).

Date: June 25–26, 1998.

Time: 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Woodfin Suite Hotel, 1380 Piccard Drive, Rockville, MD 20850.

Contact Person: Houston Baker, PhD, Scientific Review Administrator, Center for