

Dated: April 2, 2001.

Reesa L. Nichols,

NCI Project Clearance Liaison.

[FR Doc. 01-8677 Filed 4-6-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute

Development of SH2 Domain Antagonists

An opportunity is available for a Cooperative Research and Development Agreement (CRADA) for the purpose of collaborating with the NCI intramural Laboratory of Medicinal Chemistry (LMC) on further research and development of U.S. government-owned technology encompassed within U.S. Patent Application Serial Nos. 60/126,047 entitled "Phenylalanine Derivatives" 60/226,671 entitled "SH2 Domain Binding Inhibitors"; and, 60/221,525 entitled "Inhibition of Cell Motility and Angiogenesis".

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

ACTION: Notice of opportunity for Cooperative Research and Development Agreement (CRADA).

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, 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 SH2 domain antagonists potentially useful for the treatment of cancers wherein the role of hepatocyte growth factor (HGF) in stimulating tumor invasiveness and metastasis is well-established. 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 Transfer 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. Terrence Burke, Jr., Principal Investigator, Laboratory of Medicinal Chemistry, National Cancer Institute-Frederick, Bldg. 376, Rm 210, Frederick, MD 21702-1201 (phone: 301-846-5906; fax: 301-846-6033; e-mail tburke@helix.nih.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 May 9, 2001. 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 LMC, NCI, have discovered a novel class of compounds that bind with high affinity to Grb2 SH2 domains in extracellular assays and block Grb2-associated signaling in whole cell systems. These agents have been shown to inhibit Met-dependent growth factor-stimulated cell migration at low nanomolar concentrations. Details are in U.S. Patent Application Serial Nos. 60/126,047, 60/226,671 and 60/221,525 available under an appropriate Confidential Disclosure Agreement.

Technology Sought

Accordingly, DHHS now seeks collaborative arrangements to provide more extensive biological evaluation of both current and new inhibitors to Grb2-associated signaling under development within the Laboratory of Medicinal Chemistry, NCI. The ultimate purpose of the collaboration would be to develop the most promising agents into clinical trials against Met-dependent cancers. 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 commercial opportunities.

NCI and Collaborator Responsibilities

The role of the LMC, 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: Conducting extracellular ligand binding assays and providing IC₅₀ values against a wide panel of relevant SH2 domains, including Grb2 SH2 domain, as well as protein-tyrosine binding domains and other potentially relevant signal transduction targets; conducting thorough examinations in whole cell assays of effects of inhibitors on intracellular signaling phenomena; examination of effects of inhibitors on cellular mitogenesis, motility, invasiveness and anti-angiogenic properties; conducting animal studies using relevant tumor model systems.

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: March 29, 2001.

Kathleen Sybert,

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

[FR Doc. 01-8678 Filed 4-6-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel.

Date: April 17, 2001.

Time: 11:30 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: 45 Natcher Bldg., Rm 5As.25u, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: John R. Lymangrover, PhD., Scientific Review Administrator, National Institutes of Health, NIAMS, Natcher Bldg., Room 5As25N, Bethesda, MD 20892, 301-594-4952.

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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: April 2, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; 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: National Institute of Dental and Craniofacial Research Special Emphasis Panel 01-18, Review of R01 Grants.

Date: April 25, 2001.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Anna Sandberg, PhD., Scientific Review Administrator, National Institute of Dental & Craniofacial Res., 45 Center Drive, Natcher Building, Rm. 4AN44F, Bethesda, MD 20892, (301) 594-3089.

Name of Committee: National Institute of Dental and Craniofacial Research Special

Emphasis Panel 01-36, Review of P01, Interview of Applicant.

Date: May 4, 2001.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: H. George Hausch, PhD., Chief, 45 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594-2372.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 01-38, Review/Interview site visit.

Date: May 23-24, 2001.

Time: 7:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, Bethesda, MD 20814.

Contact Person: H. George Hausch, PhD., Chief, 45 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594-2372.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 01-40, RFA Review-Oral Cancer Prevention.

Date: June 15, 2001.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Deborah P. Beebe, Chief, Rockledge Center II, 6701 Rockledge Drive, Suite 7178, Bethesda, MD 20892-7924, 301/435/0270, beebed@nih.gov.

(Catalogue of Federal Domestic Assistance program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 2, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material,