

Therapeutics Program (DTP), Screening Technologies Branch (STB), on further research and development to optimize chemical structures of lead compounds exhibiting molecular-targeted anticancer, antiviral and/or antimicrobial activities.

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

**ACTION:** Notice of opportunities for cooperative research and development.

**SUMMARY:** Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710, as amended; and Executive Order 12591 of April 10, 1987), 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) for collaborative optimization of small-molecule screening leads for potency and pharmaceutical properties consistent with clinical development. The leads have been identified by STB using high-throughput screening and preliminary structure/activity study of >140,000 samples from the NCI Repository addressing a number of molecular targets of potential therapeutic significance. More specifically, a medicinal chemistry partner is sought for collaborative R&D to identify and resolve potential structural problems/features related to toxicity, formulation, chemical stability, metabolism, etc. Based on this analysis, lead compounds may be directly subjected to secondary and *in vivo* testing or a series of derivatives/analogs may be designed to obviate problems. In a second stage, *in vivo* active compounds will be subjected to additional analysis and analogs will be synthesized to further optimize structure/activity properties. Any CRADA for the biomedical use of this technology will be considered. The CRADA would have an expected duration of one to five years. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborator will have an option to elect a non-exclusive or exclusive commercialization license to subject inventions arising under the CRADA and which are subject of the CRADA Research Plan.

**ADDRESSES:** Proposals and questions about this CRADA opportunity may be addressed to Bjarne Gabrielsen, Ph.D., Technology Transfer Branch, National

Cancer Institute-Frederick, Fairview Center, Room 500, Frederick, MD 21701 (phone: 301-846-5465, fax: 301-846-6820).

Scientific inquiries should be directed to: Robert Shoemaker, Ph.D., Chief, Screening Technologies Branch, Developmental Therapeutics Program, Bldg. 440, P.O. Box B, National Cancer Institute, Frederick, MD 21702 (phone 301-846-6845; FAX 301-846-6844; e-mail: [shoemaker@dtphx2.ncifcrf.gov](mailto:shoemaker@dtphx2.ncifcrf.gov).)

**DATES:** Inquiries regarding CRADA proposals and scientific matters may be forwarded at any time. Confidential CRADA proposals, preferably two pages or less, must be submitted to the NCI. Review of proposals will begin within 90 days from date of this publication and will continue until a suitable collaborator(s) is identified. Guidelines for preparing full 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**

DTP scientists within the STB have extensive experience with both cell-free and cell-based molecular targeted screens and a track record of moving screening discoveries into clinical testing. Targeting the HIF-1- $\alpha$  (Hypoxia Inducible Factor-1) and CEBP- $\alpha$  (CCAAT/Enhancer Binding Protein  $\alpha$ ) signaling pathways relevant to cancer are among the current top priorities. Substantial effort has also been directed recently towards identification of novel inhibitors of HIV-1 assembly. Additional opportunities are anticipated.

**Technology Sought**

Accordingly, DHHS now seeks collaborative arrangements for chemical optimization of drug screening leads. The successful Collaborator should possess experience in the following areas at a minimum: Evaluation of structural features of lead molecules, design of derivative molecules with advantageous properties, solid and solution phase synthesis of individual compounds and focused libraries, molecular modeling of ADME drug properties, etc. For collaborations with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide equitable distribution of intellectual property rights developed under the CRADA. CRADA aims will include rapid publication of research results as well as development of the technology toward commercialization. The role of

the National Cancer Institute-Screening Technologies Branch 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 reagents (such as authentic standards for lead molecules) 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 as outlined in the CRADA Research Plan.

4. Accomplishing objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

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

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

7. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

8. 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.

9. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern patent rights to CRADA inventions.

Dated: November 1, 2002.

**Kathleen Sybert,**

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

[FR Doc. 02-28540 Filed 11-7-02; 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.

#### **New Gene Expressed in Prostate Cancer and Methods of Use**

TK Bera, C Wolfgang, I Pastan (NCI), B Lee, J Vincent;

DHHS Reference No. E-005-2002 filed Nov. 14, 2001;

Licensing Contact: Jonathan Dixon; 301/435-5559; [dixonj@od.nih.gov](mailto:dixonj@od.nih.gov).

A new polypeptide is described in this invention that is specifically detected in the cells of the prostate. This polypeptide has been termed Novel Gene Expressed In Prostate (NGEP). There are potential claims to the NGEF gene, polynucleotides encoding NGEF, antibodies to NGEF, methods for using an NGEF polypeptide, polynucleotide, or antibody, and pharmaceutical compositions containing any of the above NGEF-related molecules. This invention might be useful in prostate cancer diagnostics, such as an assay to detect prostate cancer, or as a therapeutic directed towards prostate cancer.

#### **Use of Interferon-Inducible 2',5'-Oligoadenylate-Dependent RNase in the Diagnosis, Prognosis, and Treatment of Prostate Cancer**

J. Carpten (NHGRI), J. Trent (NHGRI), J. Smith, P. Walsh, W. Isaacs, D. Stephan, and N. Nupponen (NHGRI);

PCT Application PCT/US02/19516 (DHHS Ref. E-196-01/1), claiming priority to a U.S. Provisional Patent Application filed on June 20, 2001;

Licensing Contact: Brenda Hefti; 301/435-4632; [heftib@od.nih.gov](mailto:heftib@od.nih.gov).

This invention pertains to the use of interferon-inducible 2',5'-oligoadenylate-dependent RNase L in the diagnosis, prognosis and treatment of cancer, particularly prostate cancer. The inventors have identified a potential prostate cancer susceptibility

locus, which has been designated HPC1 due to its putative link to hereditary prostate cancer. HPC1 may lead to an early, sensitive and accurate method for detecting cancer or a predisposition to cancer, especially prostate cancer, in a mammal. In addition, such claimed methods can be used to monitor onset and progression of cancer, as well as a patient's response to a particular treatment.

#### **Signal Transduction Inhibitor Compounds in Clinical Trials as Cancer Therapeutics**

Elise C. Kohn, Lance A. Liotta, Christian C. Felder (NCI);

U.S. Patent 5,359,078 issued October 25, 1994;

U.S. Patent 5,482,954 issued January 9, 1996;

U.S. Patent 5,498,620 issued March 12, 1996;

U.S. Patent 5,705,514 issued January 6, 1998;

U.S. Patent 5,880,129 issued March 9, 1999;

Licensing Contact: Brenda Hefti; 301/435-4632; [heftib@od.nih.gov](mailto:heftib@od.nih.gov).

The above issued patents relate to azole, diazole, and triazole compounds that appear to inhibit signal transduction and inhibit invasion and metastasis of malignant solid tumors. A number of these compounds are in phase I, II and III clinical trials for specific indications, and might be useful in other indications as well.

These issued patents claim a number of compositions of matter, pharmaceutical compositions of said compounds, and methods of using said compounds.

Dated: November 4, 2002.

**Jack Spiegel,**

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

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##### **National Institutes of Health**

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#### **Tissue Microosmometer**

Ferenc Horkay, Peter J. Bassar, Adam Berman (NICHD)

DHHS Reference No. E-280-2002/0 filed Aug. 07, 2002

Licensing Contact: Dale Berkley; 301/435-5019; [berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)

This new tissue microosmometer allows for the quantification of minor changes in the swelling properties of different tissues (e.g. cartilage) using very small amounts of tissue, and can be used as a potential diagnostic technique to detect early stages of cell or tissue injury such as cartilage degeneration or disorder. Varying the vapor pressure in the environment of the device induces controlled changes in the osmotic pressure of a tissue layer attached to the surface of a flat quartz crystal. Variation in the swelling degree is measured with high sensitivity and reliability by monitoring the change in resonance frequency of the quartz crystal. The device requires less than one microgram of sample, and the small tissue sample allows for an extremely fast response time. The device is well suited to the study of expensive or limited availability biological or macromolecular samples.

#### **Method for Convection Enhanced Delivery of Therapeutic Agents**

Edward H. Oldfield (NINDS)

DHHS Reference No. E-202-2002/0 filed Sep. 24, 2002

Licensing Contact: Dale Berkley; 301/435-5019; [berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov)

The invention is a method for monitoring the spatial distribution of therapeutic substances by MRI or CT that have been administered to tissue using convection-enhanced delivery, a technique that is the subject of NIH-owned U.S. Patent No. 5,720,720. In one embodiment, the tracer is a molecule,