

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.

**Study Goal:** The goal of this study is to plan and implement a multicenter clinical investigation into combination antiviral therapy of patients with chronic hepatitis C infected with HCV genotype 1.

Applicants must include a description of investigators and staff with experience and expertise to collaborate in multicenter clinical studies to assess combination antiviral therapy of patients with chronic hepatitis C infected with HCV genotype 1. Applicants must give evidence of their ability and experience to conduct multicenter clinical trials, with patients with chronic hepatitis C. If applicants have particular expertise and accomplishments in recruiting individuals from minority groups, these should be described.

Applicants should provide a detailed description of the pharmacokinetics of the proposed drugs to be used including how and when the drugs should be taken. The process for biologic sample collection, storage and handling needs must be included. A description of the laboratory tests that are needed including assays to determine interferon levels along with appropriate methods for performing them should be provided, as well as other core facilities and interactions with core facilities that are needed. Also included should be the methods that would be used to assure privacy and maintain confidentiality of data. How the drug will be sent to each participating center as well as packaging, storing, and accountability issues must be presented.

**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 methods to be utilized in the investigation of combination antiviral therapy of patients with chronic hepatitis C infected with HCV genotype 1 and clearly describe important issues surrounding viral resistance to interferon in hepatitis C.

2. The statement should include a detailed plan demonstrating the ability to provide sufficient quantities of the therapeutic medication agents in a timely manner for the duration of the study.

3. The statement should may include 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 viral resistance to interferon in hepatitis C, 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>).

Dated: July 27, 2001.

**Jack Spiegel,**

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

[FR Doc. 01-19640 Filed 8-6-01; 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 contacting Matthew Kiser at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7735 ext. 224; fax: 301/402-0220; e-mail: [kiserm@od.nih.gov](mailto:kiserm@od.nih.gov). A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Anticancer Effects of Novel Vitamin D Receptor Antagonists

Julianna Barsony (NIDDK); DHHS Reference No. E-213-01/0 filed 20 Jun 2001

The present invention relates to cancer therapeutics. Specifically, this invention relates to novel selective vitamin D receptor modulators (SEDM), also known as vitamin D receptor antagonists. Methods of treatment resulting in inhibition of cell growth, inducement of cell differentiation, inhibition of breast cancer growth, and inhibition of parathyroid hormone secretion in mice are disclosed.

Vitamin D does not have significant biological activity. Rather, it must be metabolized within the body to its hormonally active form, calcitriol. Calcitriol acts through the vitamin D receptor (VDR) to regulate important functions, such as calcium homeostasis, cell proliferation and differentiation, and immune functions. Many cancers contain VDR and, therefore respond to calcitriol. In such cancers, low concentrations of calcitriol stimulate growth and high concentrations inhibit growth. High doses of calcitriol and calcitriol analogues, however, cause hypercalcemia, limiting the use of this hormone for cancer treatment.

The present invention relates to derivatives of calcitriol that have been synthesized in a manner similar to the principles developed to create estrogen receptor modulators (SERM). These vitamin D receptor modulators bind well to VDR, inhibit their ability to stimulate cancer cell growth and increase their ability to induce cell differentiation. In mice, SEDM inhibited human breast cancer growth without causing hypercalcemia. The technology disclosed herein may also be used for the prevention of breast cancer, treatment and/or prevention of other types of conditions or diseases, such as, but not limited to, prostate, colorectal, and lung cancers, leukemia, primary or metastatic melanoma, glyoma, and parathyroid diseases.

### Method of Treating Cutaneous T-Cell Lymphoma by Administering a Histone Deacetylase Inhibitor

Susan Bates, Tito A. Fojo, Richard Piekarz (NCI), DHHS Reference No. E-123-00/0 filed 18 Aug 2000

The subject invention provides a method of treating cutaneous T-cell lymphoma and peripheral T cell lymphoma in a mammal. The method comprises administering to the mammal an effective amount of a histone deacetylase inhibitor. Preferably, the histone deacetylase inhibitor is a depsipeptide, in particular the depsipeptide known as NSC 630176. The method can further comprise (i) administering a steroid, a P-glycoprotein multiple drug resistance (MDR) antagonist, an antibody to a T-cell receptor and/or a retinoid, or any IL2 receptor targeted therapy, (ii) the use of chemotherapy, and/or (iii) the use of photochemotherapy.

Dated: July 30, 2001.

**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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be required to receive copies of the patent applications.

#### Amine Modified Random Primers for Microarray Detection

Dr. Charles Xiang and Dr. Michael J. Brownstein (NIMH), DHHS Reference No. E-098-01/0 filed 11 Apr 2001

*Licensing Contact:* Uri Reichman; 301/496-7736 ext. 240; e-mail: reichmau@od.nih.gov.

DNA Microarray technology has become one of the most important tools for high throughput studies in medical research, with applications in the areas of gene discovery, gene expression and mapping, and drug discovery. The technology requires the use of detection probes (cDNA probes, usually fluorescent) which are commonly made from single nucleotides using a template polynucleotide, such as mRNA. The standard methods of making cDNA probes suffer from problems related to reproducibility, and they generally result in poor incorporation of the fluorescent dye and in low sensitivity. The present invention relates to a new method for preparing cDNA probes. The new method overcomes the common problems exhibited by existing methods. The method utilizes amine modified random primers rather than single nucleotides, and results in highly efficient incorporation of the fluorescent dye in multiple sites in the probe. Coupling of the fluorescent dye to the amine residues is performed after the synthesis of the cDNA by reverse transcription. This novel procedure requires significantly less RNA than standard techniques. Licensees of the invention will be provided with primers and other reagents required to practice the invention.

#### Net-Trials—Clinical Trials Information System

Douglas Hageman, Dianne M. Reeves (NCI), DHHS Reference No. E-164-01/0

*Licensing Contact:* Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov.

The invention is a software-based application that supports data collection, reporting, validation and quality assurance for clinical data, where the data comprise clinical observations, patient histories, physical examinations and laboratory tests and procedures. This software is a Java based application with accompanying database that could be offered via an Internet browser to registered users. The invention is intended to offer health care sites and centers that are conducting clinical research an integrated software application for

patient, protocol, and research data management in a single application.

#### Method to Fabricate Continuous Lengths of Helical Coiled Shape Memory Wire

Theodor Kolobow (NHLBI), DHHS Reference No. E-105-00/0 filed 29 Sep 2000

*Licensing Contact:* Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov.

The invention is a method and apparatus for fabricating and storing continuous lengths of helical coil shaped memory wire for use in springs, endotracheal tubes, medical stents and as reinforcement for medical tubing (e.g. catheters). The helically coiled wire is continuously formed from a special nickel-titanium wire and spooled for storage in a straightened form. When the wire is later unspooled, it will snap back into the desired helical coil form.

In one method of the invention, Nitinol wire is passed through a spring forming unit to curve the wire. The so formed coil is then loosely guided along a cylindrical mandrel, passed through a high temperature oven so that the helical coil shape will be memorized, and then uncoiled and stored in a straightened form. The method provides a very thin wire with great strength and integrity of shape that resists kinking or collapse in most medical applications.

Dated: July 27, 2001.

**Jack Spiegel,**

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

[FR Doc. 01-19642 Filed 8-6-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Eye Institute; 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