Dated: November 26, 2003.

Julie Brown,

Acting, Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–30200 Filed 12–4–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute (NHLBI): Opportunity for Cooperative Research and Development Agreements (CRADAs) To Develop Novel Mechanical and Biological Treatments in Interventional Cardiovascular Medicine Using X-Ray Fluoroscopy and/or Real-Time Magnetic Resonance Imaging

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) announces the opportunity for Cooperative Research and Development Agreements (CRADAs) to develop novel mechanical and biological treatments in interventional cardiovascular medicine using x-ray fluoroscopy and real-time magnetic resonance imaging. The NHLBI seeks potential Collaborators wishing to provide expertise in (1) novel biological treatments for cardiovascular disease, including agents to facilitate mobilization of bone-marrow-derived stem and progenitor cells, (2) novel agents for therapeutic angiogenesis for myocardial or peripheral artery applications, (3) novel immune-modulating agents to treat to prevent manifestations of atherosclerosis, coronary artery occlusion, or myocardial ischemia/infarction, (4) novel mechanisms of drug, gene, or cell delivery to the myocardium or skeletal muscle to treat manifestations of coronary or peripheral artery atherosclerosis, and (5) intravascular devices for real-time magnetic resonance imaging-guided treatments including but not limited to angioplasty balloons, recanalization systems, percutaneous cardiac valves, stents, endografts, and bypass grafts.

The NHLBI seeks capability statements from parties interested in entering into a potential CRADA to manufacture, prototype, and test the above-specified agents or devices leading to early clinical testing and development. The availability of private sector support may increase the feasibility of particular aspects of the final design, but the primary criterion for selecting potential collaborators is the scientific merit of proposals for developing a plan to identify novel putative therapeutic agents and devices.

The NHLBI can provide extensive preclinical and clinical support in the development of Collaborator deliverables, including animal experiments, advanced x-ray fluoroscopic and magnetic resonance imaging laboratories, and investigations conducted in the Warren G. Magnuson Clinical Center at the Bethesda campus of the National Institutes of Health.

The control of clinical trials shall reside entirely with the Institute and the scientific participants of the trial. In the event that any adverse effects are encountered which, for legal or ethical reasons, may require communication with the U.S. Food and Drug Administration, the relevant collaborating institutions will be notified. Neither the conduct of the trial nor the results should be represented as an NHLBI endorsement of the agent, drug, or device under study.

DATES: Only written CRADA capability statements received by the NHLBI within 21 days of publication of this notice will be considered during the initial design phase. Confidential information must be clearly labeled. Potential collaborators may be invited to meet with the Selection Committee at the Collaborators' expense to provide additional information. The Institute may issue an additional notice of CRADA opportunity during the design phase if circumstances change or if the design alters substantially.

For Additonal Information and Questions: Capability statements should be submitted to Ms. Peg Koelble, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Suite 6018, Bethesda, MD 20892–7992; Tel: 301–594–4095; Fax: 301–594–3080; email: *koelblep@nhlbi.nih.gov*.

Capability Statements: A Selection Committee will use 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 NHLBI 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 method to be used in the development of novel candidate biological treatments, delivery systems, or real-time MRI-guided mechanical treatments for cardiovascular disease.

2. The statement should include a detailed plan demonstrating the ability to provide sufficient capacity in drug, gene, or stem cell development and manufacturing or in mechanical device prototyping, testing, development, and manufacturing.

3. The statement may include outline measures of interest to the Collaborator. The specifics of the proposed outcome measures and the proposed support should include but not be limited to: expertise in the proposed field, specific personnel allocation to the proposed collaboration, specific internal or external funding commitment to support the advancement of scientific research, services, facilities, equipment, or other resources that would contribute to the conduct of the commerical development.

4. The statement must address willingness promptly to publish research results and ability to be bound by PHS intellectual property policies (*see* CRADA: *http://ott.od.nih.gov/newpages/crada.pdf*).

Dated: November 26, 2003.

Carl Roth,

Associate Director for Scientific Program Operation, National Heart, Lung, and Blood Institute.

[FR Doc. 03–30206 Filed 12–4–03; 8:45 am]

BILLING CODE 4140–01–M

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 an agency 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.

Methods of Preparing Lymphocytes That Express Interleukin-2 and Their Use in the Treatment of Cancer

Ke Liu and Steven Rosenberg (NCI).
PCT Application No. PCT/US02/33243 filed 15 Oct 2002 (DHHS Reference No. E–297–2002/0–PCT–01).
Licensing Contact: Jeffrey Walenta; 301/435–4633; *walentaj@mail.nih.gov*.

Adoptive immunotherapy strategies are highly dependent upon a sustained immune response to a tumor specific antigen. An effective adoptive strategy should ideally recruit and integrate into the existing components of a cancer patient's inherent immune system. However, most cancer patient's immune systems are unable to sustain the expansion of introduced tumor specific T-cells and hence cannot sustain a tumor specific response. Interleukin 2 (IL–2) is a natural cytokine that will promote the growth and expansion of introduced tumor specific T cells. Unfortunately, supplementing a patient's immune system with the systemic introduction of IL–2 has severe toxicity effects at a dose sufficient to promote T-cell growth, limiting the effectiveness of many adoptive strategies.

This invention relates to methods of preparing autologous T-lymphocytes and tumor-infiltrating lymphocytes that express IL–2. This method comprises the following steps: obtaining peripheral blood mononuclear cells (PBMC) or tumor infiltrating lymphocytes (TIL) from a patient immunized with an antigen of cancer; stimulating the PBMC's or TIL with the antigen of the cancer *in vitro*; transducing the PBMC's or TIL with a retroviral vector encoding IL–2; and reintroducing these autologous T-lymphocytes back into the patient. This method overcomes the potential toxicity issues from systemic IL–2 delivery and creates self-sufficient T-cells for an effective adoptive immunotherapy response.

Catalytic Domains of β(1,4)-galactosyltransferase I Having Altered Donor and Acceptor Specificities, Domains That Promote In Vitro Protein Folding, and Methods for Their Use

Pradman Qasba (NCI), Boopathy Ramakrishnan (NCI), Elizabeth Boeggeman (NCI).
U.S. Provisional Application No. 60/439,298 filed 10 Jan 2003 (DHHS Reference No. E–230–2002/0–US–01); U.S. Provisional Application No. 60/450,250 filed 23 Feb 2003 (DHHS Reference No. E–230–2002/1–US–01).
Licensing Contact: Peter Soukas; 301/435–4646; *soukasp@mail.nih.gov*.

β(1,4)-galactosyltransferase I catalyzes the transfer of galactose from the donor, UDP-galactose, to an acceptor, N-acetylglucosamine, to form a galactose-β(1,4)-N-acetylglucosamine bond. This reaction allows galactose to be linked to an N-acetylglucosamine that may itself be linked to a variety of other molecules. The reaction can be used to make many types of molecules having great biological significance. For example, galactose-β(1,4)-N-acetylglucosamine linkages are very important for cellular recognition and binding events as well as cellular interactions with pathogens, such as viruses. Therefore, methods to synthesize these types of bonds have many applications in research and medicine to develop pharmaceutical agents and improved vaccines that can be used to treat disease.

The present invention is based on the surprising discovery that the enzymatic activity of β(1,4)-galactosyltransferase can be altered such that the enzyme can make chemical bonds that are very difficult to make by other methods. These alterations involve mutating the enzyme such that the mutated enzyme can transfer many different types of sugars from sugar nucleotide donors to many different types of acceptors. Therefore, the mutated β(1,4)-galactosyltransferases of the invention can be used to synthesize a variety of products that, until now, have been very difficult and expensive to produce.

The invention also provides amino acid segments that promote the proper folding of a galactosyltransferase catalytic domain. The amino acid segments may be used to properly fold the galactosyltransferase catalytic domains of the invention and thereby increase their activity. The amino acid segments may also be used to increase the activity of galactosyltransferases that are produced recombinantly. Accordingly, use of the amino acid segments according to the invention allows for production of β(1,4)-galactosyltransferases having increased enzymatic activity relative to β(1,4)-galactosyltransferases produced in the absence of the amino acid segments.

Some of the many uses for this invention are the following: synthesis of polysaccharide antigens for conjugate vaccines, glycosylation of monoclonal antibodies, and as research tools.

Targeting of the Hepatitis A Cellular Receptor To Treat Renal Cancer

Gerardo Kaplan (FDA).
U.S. Provisional Patent Application No. 60/442,286 filed 24 Jan 24 2003 (DHHS Reference No. E–227–2002/0-US–01).
Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov*.

Tumor markers—receptors on the cell surface that are expressed preferentially in tumor cells—are extremely useful in the diagnosis and treatment of cancers. The inventors have discovered that hHAVcr-1 is such a tumor marker because it is overexpressed in renal cell carcinomas, and its degree of overexpression is correlated to the stage of the tumor. In addition, overexpression of this receptor appears to affect differentiation.

The inventors have also demonstrated that they can target this receptor specifically in vitro, using monoclonal antibodies tagged with toxins and hepatitis A virus vectors. This discovery might be useful as a tumor marker or for gene-based therapeutics. Antibodies against the receptor encoded by hHAVcr-1 might be useful in an antibody-based therapeutic for the treatment of renal cancer.

Novel 2–Alkoxy Estradiols and Derivatives Thereof

Ravi Varma (NCI).
U.S. Patent Application No. 09/041,212 filed on 12 Mar 1998, which issued as U.S. Patent 6,136,992 on 24 October 2000 (DHHS Reference No. E–188–1998/1–US–01); U.S. Provisional Application No. 60/040,540 filed 13 Mar 1997 (DHHS Reference No. E–188–1998/0–US–01).
Licensing Contact: George Pipia; 301/435–5560; *pipiag@mail.nih.gov*.

The present invention is directed to novel 2-alkoxy estradiols and derivatives of 2-alkoxy estradiols having anticancer activity as claimed in the U.S. Patent 6,136,992. The invention is also directed to methods of preparing these novel compounds. These compounds have improved activity against a wide variety of tumor cell lines, including lung, colon, central nervous system, melanoma, ovarian, renal, prostate and breast cancers, compared with 2-methoxy estradiols. It is expected that these compounds will be very useful in the treatment of a wide variety of cancers. In addition, the present compounds have a low affinity for the estrogen receptor and are, therefore, expected to have fewer side effects than estradiols.

Dated: November 25, 2003.

Steven M. Ferguson,

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

[FR Doc. 03–30207 Filed 12–4–03; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Disease; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, November 25, 2003, 9 a.m. to November 25, 2003, 11 a.m. National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD, 20892 which was published in the Federal Register on October 31, 2003, 68 FR 62902.

The meeting will be held on December 18, 2003 from 3 p.m. until 5 p.m. The meeting is closed to the public.

Dated: November 28, 2003.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–30202 Filed 12–4–03; 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 property.

Name of Committee: National Institute of Diabetes and Digestive Kidney Diseases Special Emphasis Panel, Chronic Kidney Disease.

Date: December 12, 2003.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892, (301) 594–7799, *ls38z@nih.gov.*

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. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hermatology Research, National Institutes of Health, HHS)

Dated: November 28, 2003.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–30203 Filed 12–4–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Special Emphasis Panel.

Date: December 10, 2003.

Time: 10:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: David I. Sommers, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6144, MSC 9606, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@mail.nih.gov.*

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. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: November 28, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–30204 Filed 12–4–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

The meeting will be open to the public with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: December 8–9, 2003.

Time: December 8, 2003, 8:30 a.m. to 5 p.m.

Agenda: NICHD Director's Report presentation, Regional Research Networks, and an update on the Rehabilitation Medicine Scientist Training Program.

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

Time: December 9, 2003, 8:30 a.m. to 12 p.m.

Agenda: Other business dealing with the NABMRR Board.

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

Contact Person: Ralph M. Nitkin, PhD, Director, BSCD, National Center for Medical Rehabilitation Research, National Institute of Child Health and Human Development, NIH, 6100 Building, Room 2A03, Bethesda, MD 20892, (301) 402–4206.

This notice is being published less than 15 days prior to the meeting due to the timing