DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

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.

Immunogenic Peptides and Methods of Use for Treating Prostate and Uterine Cancers

Description of Technology: Cancer of the prostate is the most commonly diagnosed cancer in men and the second leading cause of cancer death in men. Despite the use of standard therapy, including surgery, radiotherapy, chemotherapy, and/or hormonal therapy more than 30,000 men will die from prostate cancer. Moreover, current therapy has limited success against metastatic androgen insensitive prostate cancer. A potential treatment for prostate cancer is immunotherapy, either alone or in combination with standard therapies.

PAGE4 is an X chromosome-linked cancer-testis antigen that is highly expressed in prostate and uterine cancers. To this end, Drs. Jeffery Schlom, Kwong Tsang, and Ira Pastan have identified and characterized novel PAGE4 cytotoxic T-cell lymphocyte (CTL) epitopes and enhanced agonist epitopes. Preclinical studies performed by Dr. Schlom and colleagues indicate that the PAGE4 agonist epitopes bind HLA–A2 molecules at lower peptide concentrations, form more stable peptide HLA–A2 complexes, induce higher levels of production of INF-gamma, Granzyme B, TNF-alpha, IL–2, and lymphotactin by PAGE4 specific T-cell lines, and T-cell lines generated against the agonist peptide were more efficient at lysing human tumor cells expressing native PAGE4. Thus, these agonist epitopes of PAGE4 could be incorporated into immunotherapy protocols, and may constitute an alternative and/or additional approach for the treatment of PAGE4 expressing prostate and uterine cancers.

Development Status: The Laboratory of Tumor Immunology and Biology plans to initiate clinical studies utilizing this technology and collaborative opportunities may be available.

Inventors: Jeffrey Schlom, Kwong-Yok Tsang, Ira H. Pastan (NCI).

Publications: Publications which may provide background information for this technology include:

1. J Yokokawa *et al.*, ''Identification of cytotoxic T-lymphocyte epitope(s) and its agonist epitope(s) of a novel target for vaccine therapy (PAGE4),'' *Int J Cancer.* 2007;121:595–605.

2. C Iavarone *et al.*, ''PAGE4 is a cytoplasmic protein that is expressed in normal prostate and in prostate cancers,'' *Mol Cancer Ther.* 2002 Mar;1(5):329–335.

3. L Prikler *et al.*, ''Adaptive immunotherapy of the advanced prostate cancer—cancer testis antigen (CTA) as possible target antigens,'' *Aktuelle Urol.* 2004 Aug;35(4):326–330. [article in German]

Patent Status: PCT Application No. PCT/US2007/004603 filed 21 Feb 2007 (HHS Reference No. E–104–2006/0–PCT–02), claiming priority to 24 Feb 2006, entitled ''Immunogenic Peptides and Methods of Use.''

Related Technology: U.S. Patent Application No. 11/704,714 filed 09 Feb 2007 (HHS Reference No. E–028–1999/0–US–08), claiming priority to 01 Sep 1998, entitled ''PAGE–4, An X-Linked GAGE-Like Gene Expressed in Normal and Neoplastic Prostate, Testis and Uterus, and Uses Therefor.''

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Michelle A. Booden, Ph.D.; 301/451–7337; *boodenm@mail.nih.gov.*

Collaborative Research Opportunity: The Laboratory of Tumor Immunology and Biology, Center for Cancer Research, NCI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Kevin Chang, Ph.D. in the NCI Technology Transfer Center at *changke@mail.nih.gov* and/or 301–496–0477 for more information.

Diagnostic and Therapeutic Methods of Detecting and Treating Cancers of Reproductive Tissues

Description of Technology: PAGE–4 is a human X-linked gene that is strongly expressed in prostate and prostate cancer, and is also expressed in other male and female reproductive tissue (e.g., testis, fallopian tube, placenta, uterus, and uterine cancer). PAGE–4 shows similarity with the GAGE protein family, but it diverges significantly from members of the family so that it appears to belong to a separate family. This, and the existence of another gene, PAGE–2, that share more homology with PAGE–4 than with members of the GAGE family indicates that the PAGE–4 protein belongs to a separate protein family.

The specific detection of PAGE–4 might be valuable for the diagnosis of prostate and testicular tumors, as well as uterine tumors. There are sufficient differences between PAGE–4 and other members of the PAGE and MAGE proteins to produce specific antibodies. Analyses with such antibodies are needed to confirm by immunohistology the expression specificity that is seen in database and mRNA analyses, and to evaluate whether anti-PAGE–4 immunotherapy could be a promising therapeutic approach. One possibility of eliminating PAGE–4 expressing cells could be to use it as cancer vaccine. Among the many possible approaches to vaccination, one method is direct vaccination with plasmid DNA. In fact, Dr. Pastan's laboratory has been able to obtain good expression of the PAGE–4 protein with mammalian expression plasmids, and has demonstrated that DNA-immunization with such expression constructs leads to good immune responses. Hence, this method may generate anti-PAGE–4 responses, and allow us to analyze if ''PAGE–4-vaccination'' can eliminate PAGE–4 expressing cells, as a therapeutic approach towards neoplasms of the prostate, testis, and uterus.

Inventors: Ira H. Pastan, Ulrich Brinkmann, George Vasmatzis, Byungkook Lee (NCI).

Patent Status: U.S. Patent Application No. 11/704,714 filed 09 Feb 2007 (HHS Reference No. E–028–1999/0–US–08), claiming priority to 01 Sep 1998, entitled ''PAGE–4, An X-Linked GAGE-Like Gene Expressed in Normal and Neoplastic Prostate, Testis and Uterus, and Uses Therefor.''

Related Technology: PCT Application No. PCT/US2007/004603 filed 21 Feb 2007 (HHS Reference No. E–104–2006/

0–PCT–02), claiming priority to 24 Feb 2006, entitled ''Immunogenic Peptides and Methods of Use.''

Licensing Contact: Jesse S. Kindra, J.D.; 301/435–5559; *kindraj@mail.nih.gov;* or Michelle A. Booden, PhD.; 301/451–7337; *boodenm@mail.nih.gov.*

Dated: July 26, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–15056 Filed 8–2–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

ODS Analytical Methods and Reference Materials Program Stakeholders' Meeting Notice

Notice is hereby given of the National Institutes of Health (NIH) Office of Dietary Supplements (ODS) Analytical Methods and Reference Materials Program Stakeholders' Meeting to be held Monday, September 10, 2007, in the Lister Hill Auditorium on the NIH Campus in Bethesda, Maryland 20892. The meeting will begin at 9 a.m. and will be open to the public.

In fiscal year (FY) 2002, Congress addressed the need for support of analytical methods and reference materials development related to dietary supplements. The congressional appropriations language supported an increased ODS budget for several topics, including analytical methods and reference materials. The Senate language called for ''ODS to allocate sufficient funds to speed up an ongoing collaborative effort to develop and disseminate validated analytical methods and reference materials for the most commonly used botanicals and other dietary supplements.''

On February 8, 2002, ODS held a public meeting to solicit comments to assist ODS in designing an overall strategy for implementing the congressional mandate to foster development and validation of analytical methods and reference materials for dietary supplements.

In FY 2004 and 2005, Congress again used similar language supporting the Analytical Methods and Reference Materials (AMRM) program in the ODS appropriations.

The purpose of the proposed meeting on September 10, 2007, is to state the progress that has been made by the AMRM program since its inception five years ago and to receive comments on directions for the next five years. The meeting is intended to seek stakeholder comments that will assist us with the continued implementation of an overall strategy for research, development, validation, and dissemination of analytical methods and standard reference materials for dietary supplement ingredients. The sponsor of this meeting is the NIH Office of Dietary Supplements.

Registration: Ms. Channet Williams of the American Institutes of Research will be coordinating the registration for this meeting. To register, please forward your name and complete mailing address, including phone number, via e-mail to *cwilliams@air.org.* If you don't have access to e-mail, please call Ms. Williams at 301–592–2130. American Institutes for Research's mailing address is 10720 Columbia Pike, Silver Spring, Maryland 20901. Registration information, as well as background information about the AMRM program, is available at *http://www.ods.od.nih.gov.*

If you wish to make an oral presentation during the meeting, you must indicate this when you register and submit the following information: (1) A brief written statement of the general nature of the statement that you wish to present, (2) the names and addresses of the person(s) who will give the presentation, and (3) the approximate length of time that you are requesting for your presentation. Depending on the number of people who register to make presentations, we may have to limit the time allotted for each presentation.

Please Note: The NIH has instituted new security measures to ensure the safety of NIH employees and property. All visitors must be prepared to show a photo ID upon request. Visitors may be required to pass through a metal detector and have bags, backpacks, or purses inspected or x-rayed as they enter NIH buildings. For more information about the new security measures at NIH, please visit the Web site at *http://www.nih.gov/about/visitorsecurity.htm.*

Dated: July 25, 2007.

Elias A. Zerhouni,

Director, National Institutes of Health.

[FR Doc. E7–15048 Filed 8–2–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of 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 a meeting of the National Advisory General Medical Sciences Council.

The meeting will be open to the public as indicated below, 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.

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 Advisory General Medical Sciences Council,

Date: September 10–11, 2007.

Closed: September 10, 2007, 8:30 a.m. to 5 p.m.

Agenda: To Review and Evaluate Grant Applications.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 9000 Rockville Pike, Bethesda, MD 20892.

Open: September 11, 2007, 8:30 a.m. to adjournment.

Agenda: For the Discussion of Program Policies and Issues, Opening Remarks, Report of the Director, NIGMS, and Other Business of the Council.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Ann A. Hagan, PhD, Associate Director for Extramural Activities, NIGMS, NIH, DHHS, 45 Center Drive, Room 2AN24H, MSC6200, Bethesda, MD 20892–6200, (301) 594–4499. *hagana@nigms.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles,