Date and Time: The meeting will be held on Tuesday, October 26, 1999, from 8 a.m. to 3:30 p.m.

Location: The meeting will be held at the Hilton-Houston Southwest, Regency Ballroom, 6780 Southwest Freeway, Houston, TX 77074, 713–977–7911, FAX 713–974–5808.

Contact: Sheryl Lunnon-Baylor, Dallas District Office (HFR–SW1580), Food and Drug Administration, 1445 North Loop West, suite 420, Houston, TX 77008, 713–802–9095, ext. 115, FAX 713–802–0906.

Registration: Send registration information (including name, title, organization title, mailing address, telephone number, and fax number) to the contact person by October 15, 1999.

If you need special accommodations due to a disability, please contact Sheryl Lunnon-Baylor (address above) at least 7 days in advance.

Executive Summary: An executive summary of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Room 12A–16, Rockville, MD 20852, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: September 30, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–25969 Filed 10–5–99; 8:45 am]

BILLING CODE 4160–01–F

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 invention listed below is owned by an agency of the U.S. Government and is 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.

ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting J.R. Dixon, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7056, ext. 206; fax 301/402–0220; E-Mail: jd212g@NIH.GOV). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

SUPPLEMENTARY INFORMATION:

Title: ''Diagnostic and Therapeutic Methods of Detecting and Treating Cancers of Reproductive Tissues.''

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

DHHS Ref. No. E–028–99/0—Filed with the U.S.P.T.O. September 1, 1998.

Background

The basis of cancer immunotherapy as a viable option of treatment rests on the supposition that tumor-specific antigens are expressed by the tumor cells, and that immune effector mechanisms can be induced selectively to destroy these tumor cells. Although a variety of host immune effector cells have been shown to participate in the killing of tumor cells, tumor-specific CD8+ Cytotoxic T Lymphocytes (''CTL'') are highly specific and effective in mediating tumor cell killing. CTLs that recognize tumor cells have been isolated from melanoma, breast, ovarian, renal, lung, colorectal and prostrate cancer patients. Their existence suggests that there is an immune response to cancer in these patients and that its augmentation might be therapeutically beneficial. Thus, approaches based on induction of tumor-specific CTLs by therapeutic vaccines may provide an attractive alternative for treating cancer patients.

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.

Prostate Cancer

Prostate Cancer is a disease affecting approximately 1 million men in the U.S.A., with an annual incidence of around 300,000 and approximately 40,000 deaths per year. Control of primary tumor by surgical resection and/or radiation has proven effective in a number of cases, however, metastatic spread, primarily to the bone, especially at late hormone independent stages of the disease, has been more difficult to control and monitor.

The above mentioned invention is available, including any available foreign intellectual property rights, for licensing on an exclusive or non-exclusive basis.

Dated: September 28, 1999.

Jack Spiegel, Ph.D.,

Director, Division of Technology Development & Transfer, Office of Technology Transfer.

[FR Doc. 99–25950 Filed 10–5–99; 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 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