DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; 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 a meeting of the Board of Scientific Counselors of the Warren Grant Magnuson Clinical Center.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for with the review, discussion, and evaluation of individual intramural programs and projects conducted by the Clinical Center, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: The Board of Scientific Counselors of the Warren Grant Magnuson Clinical Center.

Date: December 13–14, 2000.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Clinical Center Medical Board Room, 2C116, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: David K. Henderson, MD, Deputy Director for Clinical Care, Office of the Director, Clinical Center, National Institutes of Health, Building 10, Room, 2C146, Bethesda, MD 20892, 301/402–0244.

Dated: November 4, 1999.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: ''Diagnostic and Therapeutic Methods of Detecting and Treating Cancers of Reproductive Tissues''

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

ACTION: Notice.

SUMMARY: This is notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to the U.S. Patent Application 60/098,993, entitled, ''Diagnostic and Therapeutic Methods of Detecting and Treating Cancers of Reproductive Tissues'' and corresponding foreign patent applications to IDEC Pharmaceuticals, Inc. of San Diego, California. The United States of America is an assignee of the patent rights in these inventions and the contemplated exclusive license may be limited to the use of PAGE–4 plasmid DNA and/or PAGE–4 protein as a vaccine to produce an immune response in humans to eliminate PAGE–4 expressing prostate cancer cells.

DATES: Only written comments and/or applications for a license which are received by NIH on or before January 14, 2000.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: J.R. Dixon, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804. Telephone: (301) 496–7735 ext. 206; Facsimile: (301) 402–0220, E-Mail: DixonJ@OD.NIH.GOV. A signed Confidentiality Agreement will be required to receive copies of any of the patent applications.

Technology Description

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 a cancer vaccine. Among the many possible approaches to vaccination, one method is direct vaccination with plasmid DNA. In fact, a laboratory at the NIH 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 one 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 prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7 and may be limited to the field of use of PAGE–4 plasmid DNA and/or PAGE–4 protein as a vaccine to produce an immune response in humans to eliminate PAGE–4 expressing prostate cancer cells. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the exclusive license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license [*i.e.*, completed ''Application for License to Public Health Service Inventions''] filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections will not be made available for public inspection and, to the extent permitted by law, will not be subject to disclosure under the Freedom of Information Act, 5 U.S.C. 552.