7. Participate in meetings with the Food and Drug Administration for establishment of the protocols for Phase I, II and III clinical investigations and provide liaison with the FDA.

The role of the commercial partner is expected to be as follows:

1. Obtain a commercialization license from the NIH and the WHO.

2. Assume responsibility for regulatory affairs including amending the IND as necessary.

3. Assume responsibility for preparation and formulation of the drug for all pre-Phase III safety studies and clinical trials.

4. Undertake such additional safety studies as may be required for Phase III clinical trials and for NDA submission.

5. Undertake an orderly sequence of clinical investigations of testosterone bucyclate as a hormonal methods of male contraception and for androgen replacement in other methods of male contraception.

6. Assume responsibility for preparation and filing of the NDA.

7. Assume responsibility for commercial manufacture and distribution of the final products.

8. Ensure availability of the final products to the public sector of developing countries in sufficient quantities, at a preferential price, in accordance with WHO's public sector objectives.

Selection criteria for choosing commercial partners will furthermore include, but will not be limited to the following:

1. The proposal must contain a clear statement of capabilities and experience with respect to the tasks to be undertaken. This would include experience in drug development, regulatory affairs and marketing.

2. The proposal must contain a clear and concise outline of the work to be undertaken, a schedule of significant events, an outline of objectives to be accomplished with individual and overall times frames, and details of experimental procedures and techniques to be employed.

3. The proposal must contain the level of financial support which will be supplied for the development of testosterone bucyclate.

4. Agreement to be bound by DHHS and WHO rules and regulations regarding patent rights, the ethical treatment of animals, the involvement of human subjects in clinical investigations and the conduct of randomized clinical trials.

5. Agreement with provisions for equitable distribution of patent rights to any inventions developed under the CRADA and license agreements.

DATES: In view of the high priority for developing and commercializing testosterone bucyclate, all proposals must be received no later than June 26, 1997 for priority consideration.

ADDRESSES: CRADA proposals and questions should be addressed to Dr. Diana Blithe, Contraceptive Development Branch, Center for Population Research, National Institutes of Child Health and Human Development, Room 8B 13, 6100 Executive Boulevard, Rockville, Maryland 20892 (Telephone: 301/496–1661); with a copy to Director, UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, 20, Avenue Appia, CH–1211 Geneva 27, Switzerland. Responders interested in submitting a CRADA proposal should simultaneously submit a license application concerning the above-mentioned patent rights to NIH and WHO for commercialization of products arising from the CRADA.

Requests for copies of the U.S. patent, license application forms, or questions about the licensing opportunity should be addressed to Ms. Carol Lavrich, 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. 287), with a copy to Office of the Legal Counsel, World Health Organization, 20 Avenue Appia, CH–1211 Geneva 27, Switzerland (Telephone: 00–41–22 7912685). Completed license applications should be submitted to the same addresses.

Pertinent information not yet publicly described can be obtained under a Confidential Disclosure Agreement with the appropriate agency.

Dated: May 16, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–13832 Filed 5–23–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Vaccine for Malaria

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

ACTION: Notice.

SUMMARY: This is notice in accordance with 15 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a limited field of use exclusive world-wide license to practice the invention embodied in U.S. Patent Application Serial Nos. 08/119,677 (field 09/10/93), 08/487,826 (field 06/07/95), and 08/568,459 (filed 12/07/95), entitled ''Binding Domains from Plasmodium Vivax and Plasmodium Falciparum Erythrocyte Binding Proteins,'' and related foreign patent applications, to EntreMed, Inc. of Rockville, MD. The patent rights in these inventions have been assigned to the United States of America.

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. It is anticipated that this license may be limited to vaccine for Malaria.

This prospective exclusive license may be granted unless within 60 days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

SUPPLEMENTARY INFORMATION: The patent applications identify function domains of Plasmodium proteins which can be used for the prevention or treatment of malaria. The parasite invades erythrocytes by attaching to surface receptors. The erthyrocyte binding domains of the sialic acid binding protectin (SABP) of P. falciparum and the Duffy antigen binding protein (DABP) can be used in vaccines to induce immune responses which block erythrocyte binding and invasion by P. falciparum and P. vivax meroszoites. USSN 089/487,826 further includes genes and nucleotide sequences and predicted polypeptide sequences of the P. falciparum DBL (Duffy-binding like) gene family which codes for antigenically variant binding domains.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Gloria H. Richmond, Patent Advisor, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: 301/496–7057; Facsimile: 301/402–0200; E-mail: Gloria Richmond@NIH.GOV. A signed Confidential Disclosure Agreement will be required to receive a copy of the patent applications.

Applications for a non-exclusive or exclusive license filed in response to

this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by NIH on or before July 28, 1997 will be considered.

Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 15, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–13830 Filed 5–23–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Limited Exclusive License: Radioimmunotherapy Utilizing Bismuth 213 and Monoclonal Antibodies Having Binding Specificity to Tag–72 and Human Carcinomas

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

ACTION: Notice.

SUMMARY: This 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 practice the inventions embodied in U.S. Patent Applications SN 08/299,999 and corresponding foreign patent applications entitled, ''Production Of A Single-Gene Encoded Immunoglobulin''; ''Second Generation Monoclonal Antibodies Having Binding Specificity To Tag–72 And Human Carcinomas'' (07/073,685, 07/547,336, now U.S. Patent 5,512,443, issued 4/30/96)'', and U.S. Patent Application PHS Ref. No. D–001–96/0 ''Humanized Monoclonal Antibodies Specific to TAG–72; Methods For Their Manufacture and Usage in The Treatment Or Diagnosis of Cancer'' to Bio-Nucleonics, Inc. of Miami, Florida. The patent rights in these inventions have been assigned to the United States of America, except for PHS Ref. No. D–001–96/0 in which the patent rights in this invention has been assigned to the United States of America and Dow Chemical, Inc.

The prospective exclusive license field of use may be limited to: The use of CC49 monoclonal antibodies only in conjunction with Bismuth–213 for human radioimmunotherapy (RIT) and the use of CC49 monoclonal antibodies only in conjunction with Bismuth–213 as research reagents.

DATES: Only written comments and/or applications for a license which are received by NIH on or before July 28, 1997 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: Joseph G. Contrera, M.S., J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; Telephone: (301) 496–7056 ext. 244; Facsimile: (301) 402–0220. A signed Confidentiality Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: 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. 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 license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The invention relates to a monoclonal anti-tumor antibody, designated CC49 which is a second generation monoclonal antibody of the B72.3 antibody. CC49 recognizes the tumor associated glycoprotein, TAG–72. The TAG–72 antigen is expressed on at least 75% of colorectal cancers; 85% of ovarian, endometrial, gastric, and pancreatic cancers; 60% of prostate cancers; and approximately 50% of breast and lung cancers. Of particular importance is the fact that B72.3, the first generation monoclonal antibody specific for TAG–72, was the first monoclonal antibody to be approved by the Food and Drug Administration (FDA) for *in-vivo* use.

For working with B72.3, a second generation antibody, designated CC49 was developed which is highly specific for the same TAG–72 antigen. The CC49 monoclonal antibody specific for TAG–72 glycoprotein is currently in preclinical studies, and shows superior results over B72.3. The CC49 monoclonal antibody and the gene which encodes for it, is the subject technology of this exclusive license application.

Applications for a license in the field of use filed in response of this notice will be treated as objections to the grant of the contemplated licenses. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 19, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–13833 Filed 5–23–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Vision Research Program Planning Subcommittee of the National Advisory Eye Council on June 11, 1997, Executive Plaza South, 6120 Executive Boulevard, Suite 350, Bethesda, Maryland.

The meeting will be held from 3:00 p.m. to 5:00 p.m. and will be open to the public. The purpose of the meeting is to update the subcommittee on the progress of the program planning panels in preparing their reports and to discuss the next steps in developing the Council's strategic plan. Attendance by the public will be limited to space available.

Ms. Lois DeNinno, Council Assistant, National Eye Institute, (301) 496–9110, will provide a summary of the meeting, roster of committee members, and substantive program information upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. DeNinno in advance.

Dated: May 21, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–13836 Filed 5–23–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

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 Heart,