301/402–0220; e-mail: *joycec@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent application.

Thymidylate Synthase Peptides that Bind to Thymidylate Synthase Messenger RNA

Drs. Carmen Allegra and Donna Voeller (NCI).

DHHS Reference No. E–311–00/0 filed Mar 07 2001.

Thymidylate synthase (TS) is a folate-dependent enzyme that catalyzes the reductive methylation of 2'-deoxyuridine-5'monphosphate (dUMP) by the reduced folate-5,10-methylene tetrahydrofolate to deoxythymidine 5'-monophosphate (dTMP, thymidylate). Once synthesized, dTMP is phosphorylated to dTDP and then to dTTP, which is the direct precursor for DNA synthesis. Given the direct role of TS in the biosynthesis of dTMP and the finding that inhibition of dTMP synthesis results in prompt cessation of cellular proliferation and growth, TS represents an important target for cancer chemotherapy.

Specific TS peptides have been discovered which bind to TS mRNA. These peptides may be of use in screening assays to identify agents that bind TS mRNA or that inhibit the binding of TS protein to TS mRNA. These peptides are also of use in treating subjects in conjunction with other chemotherapeutic agents, and in identifying molecules and mimetics that bind TS mRNA or bind the bimolecular complex of TS protein and TS mRNA.

The above-mentioned invention is available for licensing on an exclusive or non-exclusive basis.

Dated: January 28, 2002.

Jack Spiegel,

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

[FR Doc. 02–2908 Filed 2–6–02; 8:45 am]

BILLING CODE 4140–01–P

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 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.

Four Chimpanzee Monoclonal Antibodies that Neutralize Hepatitis A Virus

Darren Schofield, Suzanne Emerson, Robert Purcell (NIAID).

DHHS Reference No. E–356–01/0 filed Nov 07 2001.

Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; *soukasp@od.nih.gov.*

This invention claims antibodies and/or fragments thereof specific for hepatitis A virus (HAV) and the use of the antibodies in the diagnosis, prevention, and treatment of hepatitis A. Hepatitis A is the most common type of hepatitis reported in the United States, which reports an estimated 134,000 cases annually, and infects at least 1.4 million people worldwide each year. HAV is a positive sense RNA virus that is transmitted via the fecal-oral route, mainly through contaminated water supplies and food sources. HAV is thought to replicate in the oropharynx and epithelial lining of the intestines, where it initiates a transient viremia and subsequently infects the liver. Humoral immunity has been shown to provide an effective defense against Hepatitis A. Prior to the availability of the current inactivated virus vaccines, pooled human immune globulin preparations were routinely used to protect individuals traveling to areas of the world where HAV is endemic. Chimpanzees are susceptible to infection with HAV and can produce antibodies that neutralize the virus. Chimpanzee immunoglobulins are virtually identical to those of humans; thus, they have the same potential as human antibodies for clinical applications. The inventors have shown that the four chimpanzee monoclonal antibodies described in the patent application neutralized HAV strains HM–175, AGM–27, and the HM–175 VP3–070 mutant. Since only a single serotype of HAV has been identified, these antibodies are predicted to neutralize most, if not all, isolates of HAV.

N-Formyl Peptide Receptor Mediation of Platelet Chemotaxis Toward Injured Cells and Activation of Immune Response

Julie Lekstrom-Himes (NIAID), Allan Kirk (NIDDK), David Kleiner (NIAID), Meggan Czapiga (NIAID).

DHHS Reference No. E–282–01/0 filed Oct 05 2001.

Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; *soukasp@od.nih.gov.*

Formyl peptides are short peptides generated by bacterial or mitochondrial endopepdidase cleavage of the first few amino acids including the N-formyl-modified methionine group of proteins. They bind to specific receptors on phagocytic cells and platelets, and induce directed migration or chemotaxis. Human phagocytes express two N-formyl peptide receptors, FPR (N-formyl peptide receptor) and FPRL–1 (FPR-like 1), both of which couple to pertussis toxin-sensitive G proteins. FPR binds N-formyl peptides at a 1000 fold higher affinity than FPRL 1 and is attributed with inducing chemotaxis. Based on their chemotactic actions, it has been hypothesized that N-formyl peptides attract phagocytes and platelets to sites of infection and injury and therefore play an important role in microbicidal and other host defense activities. In particular, platelets carry CD154 or CD40 ligand on their surface and can provide induction of dendritic cell maturation and co-stimulatory molecule expression, thus regulating immune versus tolerance responses.

Claimed in the invention are compositions of N-formyl peptides and derivatives of N-formal peptides, use of N-formyl peptides to stimulate an immune or inflammatory response, and methods of using N-formal peptide receptor inhibitors, such as blocking antibodies or other receptor antagonists, for inhibiting inflammation. Also claimed in the invention are methods of mobilizing platelets at an injury site and methods of wound healing at an injury site comprising administering N-formal peptides to the site.

Vaccination Strategies To Provide Protection Against the Ebola Virus

Gary Nabel et al. (VRC/NIAID).

DHHS Reference No. E–241–01/0 filed Oct 01 2001.

Licensing Contact: Carol Salata; 301/496–7735 ext. 232; *salatac@od.nih.gov.*

This invention describes a method for vaccination against Ebola virus. Outbreaks of hemorrhagic fever caused by the Ebola virus, particularly the Zaire subtype, are associated with high mortality rates. The virus is very contagious, and during an outbreak, presents a threat to anybody who comes into contact with an infected person. Because the virus progresses so rapidly and the mortality rate is so high, there is little opportunity to develop natural immunity, making vaccination a promising intervention. This invention relates to a vaccine strategy employing DNA and adenoviral vectors expressing proteins associated with the Ebola virus. This vaccine strategy, a DNA prime with an adenoviral boost, elicits a protective immune response in primates. A vaccine was designed to optimize expression by incorporating genes for two subtypes of the glycoprotein (Zaire and Sudan) and minimizes toxicity by eliminating the trans-membrane region. The specific genes identified may be used for gene-based or protein-based vaccines that will prevent Ebola infection.

Novel Method for Rapidly Generating Mature Dendritic Cells from Peripheral Blood Monocytes and Myeloid Precursors

Dennis Klinman, Mayda Gursel, Daniela Verthelyi (FDA).
DHHS Reference No. E–214–01/0 filed Aug 14 2001.
Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; *soukasp@od.nih.gov.*

This application claims use of CpG oligodeoxynucleotides (ODN) to generate mature dendritic cells (DC). Also claimed in the application are synergistic use of CpG ODNs with cytokines, chemokines, or other factors to induce the maturation of monocytes to dendritic cells. Dendritic cells play a critical role in the generation of adaptive immune responses. Dendritic cells excel at presenting antigen to naive T lymphocytes. Large numbers of highly active DC are necessary for prevention and/or treatment of cancer and infectious diseases. Current processes for generating mature DC from peripheral blood mononuclear cells (PBMC) involve incubating PBMC with GM-CSF plus IL–4 for one week followed by monocyte-conditioned medium for two to seven days. These processes are inefficient, expensive and do not uniformly generate DC with full functional activity. The current invention is based on the observation that bacterial DNA and synthetic ODNs containing unmethylated ''CpG motifs'' promote the maturation of murine antigen presenting cells (APC) *in vitro*. The invention is further described in Ishii KJ et al., ''Genomic DNA released by dying cells induces the maturation of APCs,'' *J. Immunol.* 2001 Sep 1;167(5):2602–7.

Use of Sterically Stabilized Cationic Liposomes To Efficiently Deliver CpG Oligonucleotides *in vivo*

Dennis Klinman, Ihsan Gursel (FDA).
DHHS Reference No. E–215–01/0 filed Jul 27 2001.
Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; *soukasp@od.nih.gov.*

Immunostimulatory CpG oligonucleotides (ODN) show promise as immune adjuvants, anti-allergens, and immunoprotective agents. Increasing the bioavailability and duration of action of CpG ODN should improve their therapeutic utility. This invention claims use of Sterically Stabilized Cationic Liposomes (SSCL) to deliver CpG ODNs. In addition to use of SSCL to deliver CpG ODNs, SSCL-CpG compositions are also claimed in the patent application. The claimed SSCL comprise three distinct phospholipid elements, DC–CHOL (which increases liposome membrane stability while improving the uptake and encapsulation of DNA), DOPE (a pH-sensitive neutral lipid that improves the cytosolic delivery of CpG ODNs following internalization), and PEG–PE (which stabilizes the liposome and also facilitates cellular uptake). The inventors have conducted both *in vivo* and *in vitro* studies using the SSCL-CpG compositions, showing that *in vitro*, liposome-encapsulated CpG ODNs stimulated significantly more interferon-gamma (IFN-γ) production than free CpG ODNs. The *in vivo* testing the inventors completed show that SSCL encapsulation of CpG ODNs increase the magnitude and duration of the activity of the CpG ODNs *in vivo*; when CpG-SSCLs were administered to mice infected with *L. monocytogenes* (listeria), one hundred percent of the infected mice survived four weeks post-treatment. The invention is further described in Gursel I et al., ''Sterically stabilized cationic liposomes improve the uptake and immunostimulatory activity of cpg oligonucleotides,'' *J. Immunol.* 2001 Sep 15; 167(6):3324–8.

Identification of DNA Sequence Motifs That Suppress the Immune Response to CpG DNA

Dennis Klinman, Mayda Gursel, Ihsan Gursel (FDA).
DHHS Reference No. E–218–01/0 filed Sep 24, 2001.
Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; *soukasp@od.nih.gov.*

This invention claims compositions and methods for suppressing CpG oligonucleotide immunostimulatory action with suppressive motifs comprising mammalian DNA. The sequences of the suppressive motifs claimed in the application comprise multimeric repeats, which have a tendency to form ''G-tetrads,'' which suppress CpG induced immune activation. The inventors have found through *in vivo* and *in vitro* experimentation that these suppressive motifs inhibited CpG DNA induced proliferation and cytokine production. Further experimentation by the inventors has shown that ODNs containing the most said repeats were the most suppressive. There are multiple therapeutic uses for the suppressive oligodeoxynucleotides (ODNs) of the invention, such as use in the prevention or treatment of septic shock, adult respiratory distress syndrome (ARDS), or autoimmune disease. Furthermore, the inventors disclose that eliminating suppressive motifs from the plasmid backbone of DNA vaccines may improve vaccine immunogenicity by maximizing the effect of CpG motifs present in such vectors. The advantages associated with use of suppressive motifs is that therapeutics based on this technology would avoid many of the unwanted side effects associated with current immunosuppressive therapeutics.

Anti-Arthropod Vector Vaccines, Methods of Selecting, and Uses Thereof

Jesus Valenzuela, Yasmine Belkaid, Shaden Kamhawi, David Sacks, Jose Ribeiro (NIAID).
DHHS Reference No. E–122–01/0 filed Jun 19, 2001.
Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; *soukasp@od.nih.gov.*

Leishmania parasites are transmitted to their vertebrate hosts by infected phlebotomine sand fly bites. Sand fly saliva is known to enhance *Leishmania* infection, while immunity to the saliva protects against infection. This invention claims nine major salivary proteins from the sand fly vector of *Leishmania major, Phlebotomus papatasi,* nucleic acids encoding the proteins, vaccines comprising the proteins and/or nucleic acids, and methods of producing an immune response to prevent *Leshmaniasis.* The inventors have shown that one of these salivary proteins, was able to protect vaccinated mice challenged with parasites plus salivary gland

homogenates (SGH). A DNA vaccine containing the cDNA for the same protein provided this same protection. Protection lasted at least 3 months after immunization. The vaccine produced both intense humoral and delayed-type hypersensitivity (DTH) reactions. B cell-deficient mice immunized with the plasmid vaccine successfully controlled *Leishmania* infection when injected with *Leishmania* plus SGH. The invention is further described in Valenzuela JG et al., ''Toward a defined anti-*Leishmania* vaccine targeting vector antigens: characterization of a protective salivary protein,'' *J. Exp. Med.* 2001 Aug 6; 194(3):331–42.

Dated: January 28, 2002.

Jack Spiegel,

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

[FR Doc. 02–2909 Filed 2–6–02; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Program Project Review Committee, Program Project Review Committee.

Date: March 21, 2002.

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

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 5520 Wisconsin Ave, Chevy Chase, MD 20815.

Contact Person: Jeffrey H. Hurst, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20892, (301) 435–0303, *hurstj@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 29, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–2895 Filed 2–6–02; 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 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 amend. 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Ancillary Studies in Heart, Lung, and Blood, Disease Trials.

Date: March 8, 2002.

Time: 1:00 PM to 3:00 PM.

Agenda: To review and evaluate grant applications.

Place: 6701 Rockledge Drive, Rockledge II, Bethesda, MD 20892.

Contact Person: Joyce A. Hunter, PhD, Review Branch, Room 7194, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20872.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 29, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–2896 Filed 2–6–02; 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 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Multicenter Study of Hydroxyurea (MSH), Patients Follow Up Extension 1.

Date: February 20, 2002.

Time: 1:00 PM to 3:30 PM.

Agenda: To review and evaluate contract proposals.

Place: Rockledge II, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert B. Moore, PHD, Scientific Review Administrator, Review Branch, Room 7192, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892, 301–435–0287.

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. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 29, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–2897 Filed 2–6–02; 8:45 am]

BILLING CODE 4140–01–M