

applications of this technology. Specific examples of gene deletions, modifications, and/or insertions are described. Furthermore, replacement of these deleted genes with other desirable viral antigen encoding sequence(s) and/or cytokine genes in order to enhance a desired immunological response is also described. Aspects of this technology are relevant to other live virus vaccines, thus increasing the safety of such vaccines.

Anti-Vaccinia Monoclonal Antibody

Jonathan Yewdell et al. (NIAID)

DHHS Reference No. E-123-2004/0—Research Tool

The current technology describes a monoclonal antibody that reacts with a vaccinia virus protein abundantly expressed under an early viral promoter after infection of cells. The antibody is useful for quantitating vaccinia virus infected cells and for studying the function of the protein to which it binds, which is known to be a double stranded RNA binding protein involved in resistance of the virus to interferons. This antibody is available for licensing through a biological materials license agreement.

New Surrogate Marker for Diagnosis of HIV/AIDS Infection and for Evaluation of Treatment Effectiveness

Gene M. Shearer et al. (NCI)

U.S. Provisional Application 60/564,588 Filed 23 Apr 2004 (DHHS Reference No. E-045-2004/0-US-01)

This technology describes the identification of a new surrogate marker, TNF-related apoptosis-inducing ligand (TRAIL), that can be universally employed to monitor the progression of HIV infection and other conditions and diseases associated with immune system activation and immunoassays for assessing the amount of TRAIL in a biological sample. In the case of HIV infection, measuring levels of this surrogate marker can distinguish among infected individuals with high viral load, infected individuals with low viral load, and uninfected individuals. Only two surrogate markers are currently recognized by the Food and Drug Administration as clinically relevant to HIV progression, HIV viral load and the absolute number of peripheral CD4 +T cells. Tests for assessing HIV viral load employ PCR, the use of which has drawbacks, including cross-contamination. TRAIL has mechanistic implications for HIV-1 pathogenesis and directly correlates to viral load but not necessarily inversely with CD4+ T cell count. Other surrogate markers have

been proposed but do not consistently reflect AIDS progression in all individuals or may result in overlooking possible treatments that may affect disease progression but do not affect the chosen marker. Therefore, use of this new surrogate marker to assess disease progression in infected individuals and to evaluate the effectiveness of various treatment regimens has several advantages over currently used methods.

Peptide Mimotopes of Lipooligosaccharide From Nontypeable *Haemophilus influenzae* and *Moraxella catarrhalis* as Peptide Vaccines

Xin-Xing Gu (NIDCD)

U.S. Provisional Application No. 60/441,928 Filed 22 Jan 2003 (DHHS Reference No. E-344-2002/0-US-01)

PCT Application No. PCT/US04/01457 Filed 21 Jan 2004 (DHHS Reference No. E-344-2002/0-PCT-02)

U.S. Provisional Application No. 60/531,239 Filed 19 Dec 2003 (DHHS Reference No. E-083-2004/0-US-01)

U.S. Provisional Application No. 60/571,889 filed 17 May 2004 (DHHS Reference No. E-083-2004/1-US-01)

These inventions relate to peptide mimotopes of lipooligosaccharides (LOS) from nontypeable *Haemophilus influenzae* (NTHi) and *Moraxella catarrhalis* that are suitable for developing novel vaccines against the respective pathogens, for which there are currently no licensed vaccines. The mimotopes not only immunologically mimic LOS from NTHi and *Moraxella catarrhalis* but will also bind to antibodies specific for the respective LOS. NTHi and *Moraxella catarrhalis* are common pathogens that cause otitis media in children and lower respiratory tract infections in adults. The effectiveness of a vaccine could be increased by substitution of a LOS epitope with a peptide mimic. Preliminary experiments have shown that some of the mimic peptides conjugated to a carrier were as effective as their respective LOS-based vaccine in stimulating a humoral immune response in rabbits. A single consensus amino acid sequence was identified for *Moraxella catarrhalis*, while four such sequences were identified for NTHi. Thus, the identified peptides are promising candidates for developing novel vaccines for NTHi or *Moraxella catarrhalis*.

Dated: August 27, 2004.

Steven M. Ferguson,

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

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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 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.

Vectors for Wild-Type DDR1b or DDR1b Mutant, and Production of THP-1 Cell Line Expressing Two DDR1 Isoforms, DDR1a and DDR1b

Teizo Yoshimura (NCI)

DHHS Reference No.: E-243-2004/0—Research Material.

Licensing Contact: Jesse S. Kindra; (301) 435-5559; kindraj@mail.nih.gov.

This technology relates to cloning of cDNAs coding for human discoidin domain receptor (DDR1) cDNAs (clone 11A for DDR1a and Clone 11B for DDR1b) from a human lung cDNA library; a mammalian expression vector for wild-type DDR1b or DDR1b mutant, and a THP-1 cell line expressing two DDR1 isoforms, DDR1a and DDR1b. These materials are useful to study the role and signaling pathways of DDR1 and to identify agonists or antagonists of these receptors.

Additional information regarding these materials is described in: Kamohara *et al.*, "Discoidin domain receptor 1 isoform-a (DDR1a) promotes migration of leukocytes in three-dimensional collagen lattices," *FASEB J.* 15:2724-2726, 2001; Matsuyama *et al.*, "Interaction of discoidin receptor 1 isoform b (DDR1b) with collagen activates p38 mitogen-activated protein kinase and promotes differentiation of macrophages," *FASEB J.* 17:1286-1288, 2003; Matsuyama *et al.*, "Activation of discoidin receptor 1 facilitates the maturation of human monocyte-derived dendritic cells through the TNF receptor associated factor 6/TGF-beta-activated protein kinase 1 binding protein 1beta/p38alpha mitogen-activated protein kinase signaling cascade," *J. Immunol.* 171:3520-3532, 2003; Matsuyama *et al.*, "Activation of discoidin domain receptor 1 isoform b with collagen up-regulates chemokine production in human macrophages: Role of p38 mitogen-activated protein kinase and NF-kB," *J. Immunol.* 172:2332-2340, 2004.

Method for Ex-Vivo Selection and Expansion of Stimulus-Responding Primary Cells Using Selective Reversible Immortalization

Eugene Barsov, David Ott (NCI)

U.S. Provisional Application No.: 60/528,244 filed 09 Dec 2003 (DHHS Reference No. E-210-2002/0-US-01).

Licensing Contact: Mojdeh Bahar; (301) 435-2950; baharm@mail.nih.gov.

This invention is a gene transfer technique to immortalize primary cells (e.g. lymphocytes) that respond to a stimulus, such as a viral antigen (e.g. HIV toxoids), a tumor antigen, or a growth factor. The antigen or growth factor stimulates a specific subset of primary cells within a population of cells to proliferate and divide. Murine leukemia virus (MuLV)-based retroviral vectors comprising a gene or genes for immortalization are used to transfect primary cells that have been stimulated to divide. Since MuLV retroviral vectors will only infect dividing cells, only primary cells activated by the antigen or growth factor will be infected by this retroviral vector and immortalized, thereby creating an "antigen-specific trap." The primary cells to be immortalized can be in targeted tissue or in stimulated *ex vivo* culture. The transduced cells are expanded to large numbers without differentiating, and brought back to the primary cell stage by removing the introduced genes (e.g. by Cre-lox recombination). The expanded population of primary cells can then be used.

Hybrid Adeno-Retroviral Vector for the Transformation of Cells

Changyu Zheng, Brian O'Connell, Bruce J. Baum (NIDCR)

U.S. Provisional Application No.: 60/265,198 filed 30 Jan 2001 (DHHS Reference No. E-312-2000/0-US-01; PCT Application PCT/US02/02279 filed 25 Jan 2002, which was published as WO 02/061104 on 30 Jul 2002 (DHHS Reference No. E-312-2000/0-PCT-02).

U.S. Patent Application No.: 10/470,784 filed 29 Jul 2003 (DHHS Reference No. E-312-2000/0-US-03).
Licensing Contact: Jesse Kindra; (301) 435-5559; kindraj@mail.nih.gov.

The invention described and claimed in these patent applications provides for novel hybrid vectors which may be used for cell transformation either *in vivo*, *in vitro*, or *ex vivo*. The hybrid vectors, which are capable of integrating into the chromosome of the host cell and are capable of transducing dividing and non-dividing cells, have an adenoviral serotype 5 backbone and two retroviral (Moloney murine leukemia virus) elements upstream and downstream of the transgene. These elements include part of the envelope sequence, the long terminal repeat (LTR) and the packaging signal sequence (upstream), and part of the envelope sequence and LTR (downstream). Due to their hybrid nature, these vectors provide a means of efficient, reliable, long-term gene expression. Furthermore, unlike other chimeric or hybrid vector systems, only a single vector is required to deliver a transgene of interest and retroviral functional proteins are not required. The vectors are packaged and delivered via an adenoviral particle and administered directly to the target cell.

This research is described, in part, in: Zheng *et al.*, "Inclusion of Moloney murine leukemia virus elements upstream of the transgene cassette in an E1-deleted adenovirus leads to an unusual genomic integration in epithelial cells," *Virology* 2003 313:460-72, 2003; Zheng *et al.*, "Integration efficiency of a hybrid adenoretroviral vector," *Biochem Biophys Res Commun.* 300:115-20, 2003; Zheng & Baum, "Long-term expression after infection by the hybrid vector AdLTR-luc is from integrated transgene," *Biochem Biophys Res Commun.* 291:34-40, 2002.

Dated: August 31, 2004.

Steven M. Ferguson,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of a Meeting of the Scientific Advisory Committee on Alternative Toxicological Methods

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) on October 20, 2004, at the U.S. Environmental Protection Agency (EPA), 109 TW Alexander Drive, Durham, NC (Building C, Room C111, Auditorium sections A. and B). The SACATM provides advice on the statutorily mandated duties of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the activities of the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM).

The meeting is being held on October 20, 2004, from 8:30 a.m. until adjournment and is open to the public with attendance limited only by the space available. Individuals who plan to attend are strongly encouraged to register with the NTP Executive Secretary by October 13, 2004, in order to ensure access to the EPA campus (Dr. Kristina Thayer at the NTP Liaison and Scientific Review Office, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709; telephone: 919-541-5021; facsimile: 919-541-0295; or e-mail: thayer@niehs.nih.gov) or online on the NTP Web site (<http://ntp-server.niehs.nih.gov>) under "What's New." A map of the EPA campus, including visitor parking, is available at <http://www.epa.gov/rtp/transportation/parking/map.htm>. Please note that a photo ID is required to access the EPA campus.

Persons needing special assistance, such as sign language interpretation or other reasonable accommodation in order to attend, are asked to notify the NTP Executive Secretary at least seven business days in advance of the meeting (see contact information above).

Agenda

A preliminary agenda is provided below. A copy of the agenda, committee roster, and any additional information, when available, will be posted on the