

The discovery should also lead to the development of novel pharmaceutical products and methods for treating BHD skin lesions using creams containing the BHD gene product, folliculin. Such products and methods of treatment are expected to reduce the size and appearance of the benign hair follicle tumors.

The disclosed technology will provide new and exciting methodologies to correctly diagnose BHD syndrome and should lead to the development of novel pharmaceutical reagents for treatment of BHD skin lesions as well as other skin diseases.

This research is also described in: Nickerson *et al.*, *Cancer Cell* 2: 157, 2002; Zbar *et al.*, *Cancer Epidem. Bio. Prev.* 11: 393, 2002; Schmidt *et al.*, *Am. J. Hum. Genet.* 69: 876, 2001; Toro *et al.*, *Arch. Dermatol.* 135: 1195, 1999.

Dated: October 27, 2003.

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 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. 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 application 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 application.

B-Defensins as Activators of Dendritic Cells and Vaccine Carrier

Arya Biragyn and Larry Kwak (NCI). U.S. Provisional Application No. 60/421,488 filed 25 Oct 2002 (DHHS Reference No. E-342-2002/0-US-01).

Licensing Contact: Catherine Joyce; 301/435-5031; e-mail: joycec@mail.nih.gov.

Tumor antigens are known to be poorly immunogenic and attempts to elicit immune responses against the epitopes of antigens specific to tumor cells have been largely unsuccessful. The inventors have developed a cancer vaccine comprising a defensin fused to a tumor antigen or viral antigen to enhance the immunogenicity of the tumor antigen or viral antigen. The inventors have demonstrated, with animal data, that chimeric proteins comprising a defensin fused to a model tumor antigen (lymphoma-derived single-chain Fv) generate a measurable humoral and anti-tumor cellular immune response when administered to a subject. (Biragyn *et al.*, Mediators of innate immunity that target immature, but not mature, dendritic cells induce antitumor immunity when genetically fused with nonimmunogenic tumor antigens, *J. Immunology* 2001 Dec 1, 167(11):6644-6653. Also, Biragyn *et al.*, DNA vaccines encoding human immunodeficiency virus-1 glycoprotein 120 fusions with proinflammatory chemoattractants induce systemic and mucosal immune responses, *Blood* 2002 Aug 15 100(4):1153-1159.)

Recently the inventors have further discovered that murine beta-defensin 2 acts directly on immature dendritic cells as an endogenous ligand for Toll-like receptor 4 (TLR-4), inducing up-regulation of costimulatory molecules and dendritic cell maturation. (Biragyn *et al.*, Toll-like receptor 4-dependent activation of dendritic cells by beta-defensin 2, *Science* 2002 Nov 1, 298(5595):1025-1029).

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

Dated: October 24, 2003.

Steven M. Ferguson,

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Putative PEDF Receptor

Sofia P. Becerra, Luigi Notari (NEI). DHHS Reference No. E-314-2003/0-US-01 filed 07 Aug 2003.

Licensing Contact: Susan S. Rucker; 301/435-4478; ruckersu@mail.nih.gov.

This application describes compositions and methods related to Pigmented Epithelium Derived Factor (PEDF). PEDF is a protein, belonging to the serpin family, that has been demonstrated to have neurotrophic, gliastatic, neuronotrophic and anti-angiogenic properties. In particular, the compositions and methods described and claimed in this application are related to the isolation, cloning, expression and characterization of the putative receptor for PEDF. The PEDF receptor as described herein is a transmembrane protein having an extracellular ligand-binding domain, a transmembrane domain and an intracellular domain. The PEDF receptor shares some homology with an orphan receptor identified in the liver and the protein known as adiponutrin.

The isolation and cloning of the PEDF receptor will be useful in basic research to further elucidate the role of PEDF and its receptor in signal transduction

pathways. Furthermore, identification of the PEDF receptor will allow for the development of drug screening assays to identify agonists and antagonists of PEDF activity. In addition, isolation and identification of the PEDF receptor will allow new biological molecules such as monoclonal antibodies and chimeric IgG-receptor constructs to be developed.

This work has not yet been published.

Detection of Antigen-Specific T Cells and Novel T Cell Epitopes by Acquisition of Peptide/HLA-GFP Complexes

Steven Jacobson, Utano Tomaru, and Yoshihisa Yamano (NINDS).
U.S. Provisional Application No. 60/457,006 filed 24 Mar 2003 (DHHS Reference No. E-084-2003/0-US-01).
Licensing Contact: Brenda Hefti; 301/435-4632; heftib@mail.nih.gov.

This invention relates to a method for identifying specific T cell epitopes and antigen-specific T cells through labeling with an HLA-GFP complex expressed on an antigen-presenting cell. The T cells acquired the peptide-HLA-GFP complex through T cell mediated endocytosis upon specific antigen stimulation. This basic method can be used for several purposes. First, it can be used to generate a T-cell immune response through the attachment of a reporter peptide to the antigen-presenting cell. It can also be used as a way to assay a population of cells to determine whether any T cells specific for a particular antigen are present. This might be useful in applications related to autoimmunity, infectious disease, or cancer. Third, it can be used as a therapeutic to eliminate antigen-specific T cells associated with disease, if coupled to a toxic moiety.

Methods and Composition for the Diagnosis of Neuroendocrine Lung Cancer

Curtis Harris (NCI).
U.S. Provisional Application No. 60/423,380 filed 04 Nov 2002 (DHHS Reference No. E-248-2002/0-US-01).
Licensing Contact: Catherine Joyce; 301/435-5031; joycec@mail.nih.gov.

The technology relates to the use of cDNA microarrays to facilitate the identification of pulmonary neuroendocrine tumors. In order to identify molecular markers that could be used to classify pulmonary tumors, the inventors examined the gene expression profiles of clinical samples from patients with small cell lung cancer (SCLC), large cell neuroendocrine carcinoma (LCNEC), and typical carcinoma (TC) tumors by cDNA microarray analysis to detect

hybridization between cDNA from tumor cells and DNA from a panel of 8,897 human genes. Gene expression was found to be nonrandom and to exhibit highly significant clustering that divided the tumors into their assigned World Health Organization (WHO) classification with 100% accuracy. The inventors concluded that pulmonary neuroendocrine tumors could be classified based on the genome-wide expression profile of the clinical samples without further manipulations.

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

Dated: October 24, 2003.

Steven M. Ferguson,

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Enhanced HIV-1 Vaccine Cytotoxic T Cell Epitope From Conserved Region of HIV-1 Reverse Transcriptase

Jay Berzofsky, Takahiro Okazaki (NCI).
U.S. Provisional Application No. 60/459,507 filed 31 Mar 2003 (DHHS Reference No. E-044-2003/0-US-01).

Licensing Contact: Michael Ambrose; 301/594-6565; ambrosem@mail.nih.gov.

Polypeptides derived from the HIV-1 RT Catalytic site. Peptides are modified by replacement of certain key amino acid residues to increase binding to HLA-A2, the most common human class I HLA molecule. Such modified peptides are more immunogenic and can be used for further development of second-generation vaccines, therapeutics or diagnostic reagents. DNA encoding said modified polypeptides can be used as vaccines (naked DNA, bacterial or viral vector constructs).

Methods and Compositions for Selectively Enriching Microbes

Michael A. Grant (FDA/ORO).

U.S. Provisional Application No. 60/435,639 filed 20 Dec 2002 (DHHS Reference No. E-228-2002/0-US-01).

Licensing Contact: Michael Ambrose; 301/594-6565; ambrosem@mail.nih.gov.

The described technology provides for the methods, reagents and kits for the specific enrichment of microbes for further identification and diagnosis with particular emphasis on *E. coli* O157:H7 and other *E. coli*.

The technology details a 2-step process in which the primary sample is held under acid conditions to inhibit or kill competitor microbes within the sample. The acidic conditions can also contain selective agents such as phage or nutrient supplements for further selectivity. After a predetermined time, the sample is then incubated under unrestricted growth conditions for the enrichment of the remaining microbes. These are then carried through for further identification and potential diagnosis.

The technology can be used to selectively enrich for potential medically important bacteria, especially *E. coli* O157:H7, other pathogenic *E. coli*, *Shigella*, and other species.

Dated: October 24, 2003.

Steven M. Ferguson,

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

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