completer protection according to the immunogenicity data.

Application: Immunization against *Salmonella typhi* for long term prevention of typhoid fever in all ages.

Developmental Status: Conjugates have been synthesized and clinical studies have been performed. The synthesis of the conjugates is described by Kossaczka, *et al.* in Infect Immun. 1997 June;65(7):2088–2093. Phase III clinical studies are described by Mai, *et al.* in N Engl J Med. 2003 October 2; 349(14):1390–1391. Dosage studies are described by Canh, *et al.* in Infect Immun. 2004 Nov; 72(11):6586–6588.

A safety and immunogenicity study in infants are under way. The aim is to administer the conjugate vaccine with routine infant immunization. Preliminary results shows the vaccine is safe in 2 months old infants.

Inventors: Zuzana Kossaczka, Shousun C. Szu, and John B. Robbins (NICHD).

Patent Status: U.S. Patent 6,797,275 issued 28 Sep 2004 (HHS Reference No. E–020–1999/0–US–02); U.S. Patent Application No. 10/866,343 filed 10 Jun 2004 (HHS Reference No. E–020–1999/0–US–03); U.S. Patent Application No. 11/726,304 filed 20 Mar 2007 (HHS Reference No. E–020–1999/0–US–04).

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Child Health and Human Development, Laboratory of Developmental and Molecular Immunity, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize A Method of Immunizing Humans Against Salmonella Typhi Using a Vi-rEPA Conjugate Vaccine. Please contact John D. Hewes, Ph.D., at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: January 10, 2008.

Steven M. Ferguson,

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

[FR Doc. E8–1232 Filed 1–24–08; 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, HHS.

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.

Diagnosis and Treatment of Barrett's Esophagus and Associated Esophageal Adenocarcinoma

Description of Invention: Barrett's esophagus is a condition in which the normal esophageal tissue lining has been replaced by an abnormal lining of gastric and intestinal tissue resulting from chronic gastroesophageal reflux disease. Patients have an increased risk of developing esophageal adenocarcinoma, which is often detected at later stages and is associated with poor prognosis. Survival rates are very low ranging from 10% in Europe to 16% in the United States.

Available for licensing are microRNA (miRNA) biomarkers that show differential expression in the adenocarcinoma diagnosis and Barrett's esophagus status, and they can predict diagnosis and Barrett's esophagus with accuracies of 71.4% and 74.7%, respectively. Thus, these miRNA biomarkers that may predispose individuals to Barrett's esophagus and/or esophageal adenocarcinoma could provide a means for earlier detection and help in better identifying treatment options.

Applications:

Method to diagnose and treat Barrett's esophagus and esophageal adenocarcinoma.

miRNA pharmaceutical compositions to treat Barrett's esophagus.

Advantages: Early diagnostic that can more accurately stratify patients for increased survival rates and appropriate treatments.

Development Status: The technology is currently in the pre-clinical stage of development.

Market: Esophageal cancer is the 8th most common cancer and 6th most common cause of cancer worldwide.

Survival rate of esophageal cancer is 10% to 16% in Europe and United States respectively.

miRNA technologies have an emerging market, and in 2007, it was worth an estimated 23 million dollars in the U.S. and it has a projected annual growth rate of 100%.

Inventors: Ewy Mathe (NCI), Curtis C. Harris (NCI), *et al.*

Patent Status: U.S. Provisional Application No. 60/979,300 filed 11 Oct 2007 (HHS Reference No. E–008–2008/0–US–01).

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The Laboratory of Human Carcinogenesis at the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize methods to diagnose and treat Barrett's esophagus and esophageal carcinoma. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Mouse Model for Obesity and Type 2 Diabetes Due to Inactivation of ANKRD26 Gene

Description of Invention: Obesity and type II diabetes are major health hazards both in the United States and internationally. The incidence of obesity has been steadily increasing, underscoring the need to identify and develop effective treatments. As a result, there has been a strong effort to create animal models to help study these diseases.

NIH inventors have created a new mouse model for obesity and type II diabetes. In this model, both copies of the ANKRD26 gene are inactivated by the insertion of a marker gene (beta-galactosidase) into the open reading frame of the gene. The resulting knockout mouse exhibits extreme obesity, increased organ and body size,

and acquired insulin resistance. The mouse also expresses the marker gene, thereby allowing the monitoring of ANKRD26 expression patterns.

Applications:

Study and identify treatments for obesity and type II diabetes.

Examine ANKRD26 expression under various conditions.

Study the progression of obesity and type II diabetes in a specific genetic background.

Advantages:

Distinct phenotype from other mouse models for obesity and type II diabetes allows broader study of the diseases when used in combination with other mouse models.

Distinct phenotype allows the study of obesity in a previously unidentified genetic background.

Benefits: Obesity can increase the susceptibility to other health conditions such as cardiovascular disease. It has been reported that billions of tax dollars a year are spent in the treatment of obesity-attributable conditions. The use of this animal model could result in social benefit, in terms of both health and financial concerns, by leading to the development of new methods of treating obesity. Furthermore, the incidence of obesity has more than doubled over the past 10 years, suggesting that the discovery of new treatments would result in strong financial returns.

Inventor: Ira Pastan (NCI).

Publication: TK Bera *et al.* A model for obesity and gigantism due to disruption of the Ankrd26 gene. Proc Natl Acad Sci USA. 2008 Jan 8;105(1):270–275.

Patent Status: HHS Reference No. E–156–2007/0—Research Tool. Patent protection is not being sought for this technology.

Licensing Status: Available for licensing.

Licensing Contact: David A. Lambertson, PhD; 301–435–4632; *lambertsond@mail.nih.gov.*

Photosensitization by Nuclear Receptor-Ligand Complexes and Cell Ablation Uses Thereof

Description of Invention: Androgen receptors (AR) mediate the effects of male steroid hormones and contribute to a wide variety of physiological and pathophysiological conditions. Prostate cancer development and progression are mediated through AR, a ligand-dependent transcription factor, and it is present in all stages of prostate carcinoma. Increased levels of PSA, an AR-induced prostate tumor-specific protein, are indicative of prostate cancer. Benign, non-cancerous conditions are also AR-dependent and can be therapeutic targets as well.

This technology is a method to cause AR-induced cell death (apoptosis) through photoactivation of a non-steroidal androgen receptor antagonist 1,2,3,4-tetrahydro-2,2-dimethyl-6-(trifluoromethyl)-8-pyridono[5,6-g] quinoline (TDPQ). Upon TDPQ binding to AR, a highly potent photocytoxic reaction induced once the TDPQ-AR complex is exposed to visible light irradiation of a specific wavelength. The inventors have cell-culture results demonstrating that cell death is a function of TDPQ, AR and light irradiation. This treatment method can potentially target AR-containing cancerous cells, while sparing nearby cells that lack AR.

The process has been extended to other nuclear receptors by choice of other photoactivatable ligands for these receptors. Certain suitable ligands are marketed drugs.

Applications: Therapeutic compounds to treat AR related conditions such as prostate cancer, baldness, hirsutism, and acne.

Potential therapeutics for progesterone and glucorticoid receptor ligand related conditions such as breast and brain cancers, lymphoma, leukemia and arthritis.

Method to treat androgen, progesterone, and glucorticoid receptor related conditions.

Market: Prostate cancer is the second most common type of cancer among men, wherein one in six men will be diagnosed with prostate cancer.

An estimated 218,890 new cases of prostate cancer and 27,050 deaths due to prostate cancer in the U.S. in 2007.

Hirsutism affects approximately 5% of adult women in the United States.

Hair loss and acne industries are worth several billions of dollars.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: William T. Schrader *et al.* (NIEHS).

Publications:

1. B Risek *et al.* Androgen Receptor-Mediated Apoptosis is Regulated by Photoactivatable AR Ligands. Presented at the Annual Meeting of the Endocrine Society in Toronto, Canada in June 2007.

2. B Risek *et al.* Photocytotoxic Properties of the Non-Steroidal Androgen Receptor Antagonist TDPQ. Presented at the Annual Meeting of the Endocrine Society in Boston, MA in June 2006.

Patent Status: U.S. Provisional Application No. 60/926,218 filed 24 Apr 2007 (HHS Reference No. E–108–2007/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Antibodies and Polypeptides Specific to AAMP–1: Diagnostic and Therapeutic Uses Thereof

Description of Invention: Angio-associated migratory cell protein (AAMP–1) was first isolated from a human melanoma cell line as a motility-associated cell protein. AAMP–1 contains two immunoglobin domains, six WD40 repeats, and a heparin-binding domain. In vitro, over expression of AAMP–1 promotes tumor cell invasion and metastasis as well as angiogenesis. AAMP–1 was later found to be over expressed in endothelial cells, cytotrophoblasts, and poorly differentiated colon adenocarcinoma cells found in lymphatics. In addition, gene expression studies have shown that AAMP–1 is over expressed in breast and gastrointestinal tumors. The issued patents claim proteins, polypeptides, and recombinant polyclonal antibodies specific to AAMP–1 and their use in diagnostic and therapeutic applications.

Applications: The antibodies specific to AAMP–1 can detect formalin-fixed antigen and SDS-denatured antigen. These antibodies can be used for detailed expression studies of AAMP–1 in different cancer cell lines.

The antibodies could also be used to detect AAMP–1 in patient's sera as a useful diagnostic marker for multiple carcinomas including high nuclear grade ductal carcinoma in situ (Clinical Cancer Research Dec 2002 8:3788–95).

Claimed proteins and polypeptides could also be used to promote cell adhesion to a substrate, promote tissue acceptance of prostheses, and promote wound healing.

Development Status: This technology is currently in the pre-clinical stage of development.

Market: Estimated new cases and deaths from breast cancer in the United States in 2007: New cases: 178,480 (female); 2,030 (male); Deaths: 40,460 (female); 450 (male).

Inventors: Marie Beckner, Henry Krutzsch and Lance Liotta (NCI).

Publications:

1. ME Beckner *et al.* AAMP, a newly identified protein, shares a common epitope with alpha-actinin and a fast skeletal muscle fiber protein. Exp Cell Res. 1996 Jun 15;225(2):306–314.

2. A Adeyinka *et al.* Analysis of gene expression in ductal carcinoma in situ of the breast. Clin Can Res. 2002 Dec;8(12):3788–3795.

Patent Status: U.S. Patent No. 6,274,134 issued 14 Aug 2001 (HHS Reference No. E–084–1991/1–US–01); Australian Patent No. 684,806 issued 23 Apr 1998 (HHS Reference No. E–084–1991/1–AU–05); Australian Patent No. 668,134 issued 26 Apr 1996 (HHS Reference No. E–084–1991/0–AU–03) and Japanese Patent No. 3,715,313 issued 9 November 2005 (HHS Reference No. E–084–1991/1–JP–04).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Surekha Vathyam, PhD; 301–435–4076; *vathyams@mail.nih.gov.*

Dated: January 16, 2008.

Steven M. Ferguson,

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

[FR Doc. E8–1244 Filed 1–24–08; 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, HHS.

ACTION: Notice.

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Human Papillomavirus microRNA Diagnostics and Therapeutics

Description of Technology: Available for licensing and commercial development are patent rights that cover the uses of a p53 specific microRNA (miRNA). It has been reported that the tumor suppressive mRNA miR–34a is downregulated in HPV-infected primary keratinocytes. miR–34a arrests the cell cycle at G2 phase and promotes apoptosis. Therapeutic restoration of normal miR–34a expression levels and/or simultaneous stabilization of p53 (inhibited by HPV E6) may induce miR–34a accumulation in G0/G1 phase and potentially arrest tumor growth.

Applications: Cervical cancer; Human papillomavirus; Therapeutics.

Inventors: Zhi-Ming Zheng, Xiaohong Wang (NCI).

Relevant Publications:

1. WO Lui *et al.* Patterns of known and novel small RNAs in human cervical cancer. Cancer Res. 2007 Jul 1;67(13):6031–6043.

2. I Martinez *et al.* Human papillomavirus type 16 reduces the expression of microRNA–218 in cervical carcinoma cells. Oncogene 2007 Nov 12; Advance online publication, doi:10.1038/sj.onc.1210919.

Patent Status: U.S. Provisional Application No. 60/983,368 filed 29 Oct 2007 (HHS Reference No. E–029–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301/435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute HIV and AIDS Malignancy Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize HPV-induced aberrant expression of microRNAs for cervical cancer diagnostics and therapeutics. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Nitroxide Radical as a Treatment for Neurodegeneration

Description of Technology: This invention describes the use of a nitroxide radical to treat or prevent the progression of neurodegeneration characterized by a deficiency in iron regulatory protein 2 (IRP 2) function. The inventors discovered that IRP 2 null mice with adult-onset neurodegeneration and microcytic anemia regain activity of iron regulatory protein 1 (IRP 1) after eating food formulations containing specific nitroxide radicals. The inventors also discovered the nitroxide agent prevents the progression of neurodegeneration by attacking inhibitory iron-sulfur clusters found on IRP 1 thereby allowing IRP 1 to bind to iron responsive elements found on transcripts that encode iron metabolism proteins that regulate cellular iron homeostasis in the brain.

Applications: Treatment for neurological disorders resulting from a deficiency in the amount of bioavailable iron in the central nervous system, including Alzheimer's and Parkinson's disease, erythropoietic protoporphyria or adult-onset neurodegeneration.

Market: Over 22 million people suffer from neurodegenerative diseases worldwide, and in 2050, this number could triple due to increased life expectancy and an increased aging population.

Development Status: Early-stage.

Inventors: Tracey Rouault *et al.* (NICHD).

Patent Status: U.S. Provisional Application No. 60/894,134 filed 09 Mar 2007 (HHS Reference No. E–153–2007/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Charlene A. Sydnor, PhD; 301/435–4689; *sydnorc@mail.nih.gov.*

A Sensitive, High Throughput Pseudovirus-Based Papillomavirus Neutralization Assay for HPV 16 and HPV 18

Description of Technology: This invention is a research tool for measuring protective antibody responses against Human Papilloma Viruses (HPV). Sensitive high-throughput neutralization assays, based upon pseudoviruses carrying a secreted alkaline phosphatase (SEAP) reporter gene, were developed and validated by the inventors for HPV 16, HPV 18, and bovine papillomavirus 1 (BPV1). In a 96-well plate format, the assay was reproducible and appears to be as sensitive as, but more type-specific than, a standard papillomavirus-like particle (VLP)-based enzyme-linked immunosorbent assay (ELISA). The SEAP pseudovirus-based neutralization assay should be a practical method for quantifying potentially protective antibody responses in HPV natural history and prophylactic vaccine studies.

Inventors: John T. Schiller (NCI), Douglas R. Lowy (NCI), Christopher Buck (NCI), Diana V. Pastrana (NCI), *et al.*

Publication: The assay is further described in Pastrana *et al.*, ''Reactivity of human sera in a sensitive, high-throughput pseudovirus-based papillomavirus neutralization assay for HPV16 and HPV18,'' Virology. 2004 Apr 10;321(2):205–216.

Patent Status: HHS Reference No. E–137–2004/0—Research Material.