Inventors: Peter D. Burbelo and Michael J. Iadarola (NIDCR).

Related Publications:

1. Burbelo PD, Leahy HP, Issa AT, Groot S, Baraniuk JN, Nikolov NP, Illei GG, Iadarola MJ. Sensitive and robust luminescent profiling of anti-La and other autoantibodies in Sjogren's syndrome. Autoimmunity. 2009 Sep;42(6):515–524. [PubMed: 19657778]

2. Burbelo PD, Ching KH, Issa AT, Loftus CM, Li Y, Satoh M, Reeves WH, Iadarola MJ. Rapid serological detection of autoantibodies associated with Sjögren's syndrome. J Transl Med. 2009 Sep 24;7:83. [PubMed: 19778440]

3. Burbelo PD, Ching KH, Klimavicz CM, Iadarola MJ. Antibody profiling by Luciferase Immunoprecipitation Systems (LIPS). J Vis Exp. 2009 Oct 7;(32); pii: 1549; doi: 10.3791/1549. [PubMed: 19812534]

Patent Status: U.S. Provisional Application No. 61/224,649 filed 10 Jul 2009 (HHS Reference No. E–070–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Norbert Pontzer, J.D., Ph.D.; 301–435–5502; *pontzern@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Dental and Craniofacial Research, Laboratory of Sensory Biology, Neurobiology and Pain Therapeutics Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact David W. Bradley, Ph.D. at 301–402–0540 or *bradleyda@nidcr.nih.gov* for more information.

Dated: January 21, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–1680 Filed 1–27–10; 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.

Nitric Oxide-Based Therapeutics for Lung Cancer

Description of Invention: JS–36–25, a diazeniumdiolate prodrug, is available for licensing and development of treatments for lung cancer. The inventors have demonstrated a potent tumoristatic activity of JS–36–25 in both lung cancer cells in vitro and as xenografts in mice. JS–36–25 treatment led to 85% reduction of tumor growth in vivo. The tumoristatic potency of the compound correlated well with the level of endogenous reactive oxygen species (ROS) in the cancer cells. Thus, in addition to potent tumoristatic activity when administered alone, this compound is predicted to have a strong synergy with therapeutics that act through generation of ROS, such as bortezomib, doxorubicin, as well as high-energy radiation.

Applications: Development of lung cancer treatments.

Development Status: Pre-clinical.

Market: There are over 160,000 new cases of lung cancer every year in the United States alone.

Inventors: Anna E. Maciag *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 61/261,175 filed 13 November 2009 (HHS Reference No. E–025–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Steve Standley, Ph.D.; 301–435–4074; *sstand@od.nih.gov.*

T-Cell-Specific Gfi-1 Knockout Mouse

Description of Invention: This is a mouse model available to study T-cell differentiation. Growth factor independent 1 (GFi-1) is a transcriptional repressor that is transiently induced during T-cell activation. This knockout mouse line is a GFi-1[flox/flox] introduced into a mouse Cre controlled by a CD4 promoter, which allows selective removal of GFi-1 exclusively in T-cells. It has thus-far been used to demonstrate that GFi-1 plays a critical role in enhancing Th2 cell expansion and repressing induction of Th17 and CD103+ iTreg cells.

Applications: Tool for studying T-cell proliferation and differentiation.

Inventors: Jinfang Zhu and William E. Paul (NIAID).

Related Publication: J Zhu, TS Davidson, G Wei, D Jankovic, K Cui, DE Schones, L Guo, K Zhao, EM Shevach, WE Paul. Down-regulation of Gfi-1 expression by TGF-beta is important for differentiation of Th17 and CD103+ inducible regulatory T cells. J Exp Med. 2009 Feb 16;206(2):329–341. [PubMed: 19188499].

Patent Status: HHS Reference No. E–242–2009/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Steve Standley, Ph.D.; 301–435–4074; *sstand@od.noh.gov.*

Dated: January 21, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–1668 Filed 1–27–10; 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.

Preventing Oral Mucositis With Hybrid Adenoretroviral Vectors

Description of Invention: Researchers at the National Institutes of Health have recently developed a novel method utilizing adenoretroviral vectors to safely and swiftly prevent oral mucositis induced by radiotherapy. This clever new method developed by National Institute of Dental and Craniofacial Research (NIDCR) researchers combines the advantages of adenoviral and retroviral vectors to efficiently shuttle into salivary glands a non-integrating vector that can produce a therapeutic protein for intermediate to long-term treatment. This approach is anticipated to result in fewer side-effects than current therapies.

The market for the treatment of mucositis, the painful inflammation and ulceration of the mucous membranes lining the digestive tract, is estimated to be in excess of $5 billion worldwide. Up to 80% of all patients receiving radiotherapy and approximately 40% of all chemotherapy patients develop oral mucositis, and almost all patients receiving radiotherapy for head and neck cancer and those undergoing stem cell transplantation develop mucositis.

Applications

- Prevention of radiation-induced oral mucositis.
- Transduction of genes encoding secretory proteins with clinical uses for intermediate to long-term treatment (*e.g.,* 4–8 weeks).

Advantages

- Safe.
- Reduced potential for side-effects.
- Efficient production of transduced genes.
- Efficient in vivo/in vitro transduction.
- Extra-chromosomal location.

Development Status: Pre-clinical.

Inventor: Changyu Zheng *et al.* (NIDCR).

Patent Status: U.S. Provisional Application No. 61/176,210 filed 07 May 2009 (HHS Reference No. E–185–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Patrick McCue, Ph.D.; 301–435–5560; *McCuepat@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Dental and Craniofacial Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact David Bradley, Ph.D. at 301–402–0540 or *bradleyda@nidcr.nih.gov* for more information.

Mutations of the ERBB4 Gene in Melanoma

Description of Invention: Cutaneous malignant melanoma is the most common fatal skin cancer, and the incidence of this disease increases each year. The average survival time for patients diagnosed with malignant melanoma is less than ten months. Consequently, it is important to identify and understand genetic alterations leading to malignant melanoma so that new treatment strategies can be developed.

Protein tyrosine kinases (PTKs) have been associated with a wide variety of cancers, including melanoma. Using high-throughput gene sequencing, the NIH inventors have analyzed PTKs in melanoma and have identified several novel somatic alterations, including alterations in ERBB4. This invention provides methods of identifying specific inhibitors to ERBB4 that could be used to treat patients with ERBB4 mutations. Given the recent success of small molecule protein kinase inhibitors and specifically inhibitors to EGFR, this invention could be used to further the development of specific inhibitors to ERBB4 and improve existing melanoma treatments for patients with these mutations.

Applications

- Diagnostic array for the detection of ERBB4 mutations.
- Method of identifying ERBB4 inhibitors as therapeutic agents to treat malignant melanoma patients.

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

Market

- Approximately 160,000 new cases of melanoma are diagnosed worldwide each year. Malignant melanoma is increasing faster than any other cancer.
- Melanoma is the most prevalent cancer among women between the ages of 25 and 29 and the second most prevalent cancer among women ages 30–34.
- Cutaneous malignant melanoma is the most serious form of skin cancer and accounts for about 75% of all skin cancer deaths.
- One person dies from melanoma every hour.

Inventors: Yardena R. Samuels *et al.* (NHGRI).

Related Publication: Prickett TD, Agrawal NS, Wei X, Yates KE, Lin JC, Wunderlich JR, Cronin JC, Cruz P, Rosenberg SA, Samuels Y. Analysis of the tyrosine kinome in melanoma reveals recurrent mutations in ERBB4. Nature Genet. 2009 October; 41(10):1127–1132. [PubMed: 19718025].

Patent Status: PCT Application No. PCT/US2009/053005 filed 06 Aug 2009 (HHS Reference No. E–272–2008/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: Whitney Hastings, 301–451–7337; *hastingw@mail.nih.gov*.

Collaborative Research Opportunity: The Cancer Genetics Branch, National Human Genome Research Institute (NHGRI), National Institutes of Health (NIH) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate and/or commercialize an ERBB4-based diagnostic, prognostic and/or theranostic test as well as identify and/or evaluate ERBB4 inhibitor compounds for testing as possible candidate malignant melanoma therapeutic drugs. Please contact Claire Driscoll at *cdriscol@mail.nih.gov* or Dr. Yardena Samuels at *samuelsy@mail.nih.gov* for more information.

Genetically Modified Stem Cells for Personalized Therapy of Single Gene Disorders

Description of Invention: This technology is directed to individualized therapies of single gene disorders by introducing a patient's own genetically modified adult stem cells to the damaged tissue. Diseases arising from single gene disorders affect approximately 1% of the human population. Unlike most current treatments for such diseases, which are non-specific and symptom-based, this technology specifically addresses the underlying pathology of the disorder.

Many single gene diseases are accompanied by tissue damage and inflammation. This technology exploits the inflammatory response, which includes homing of mesenchymal stem cells to the site of damage, for therapeutic purposes. The inventors have genetically modified adult stem cells to produce silencing RNA specific to the defective protein in the damaged tissue. The silencing RNA can inhibit the source of the pathology and promote the growth and differentiation of genetically modified stem cells adjacent to the damaged tissue which can support the tissue healing process.

Additionally, the risk of developing Graft Versus Host Disease is eliminated by utilizing the patient's own stem cells.

Proof of concept has been demonstrated in the vascular type of the Ehlers-Danlos Syndrome (VEDS). Using tissues isolated from VEDS patients, siRNA was shown to correct the mutational defect. The siRNA not only inhibited the production of the mutant protein but also restored the normal, non-pathological structure of the wild-type protein in the tissue.

This technology may be particularly applicable to patients with mutations in structural proteins of the extracellular matrix, as presented in diseases such as osteogenesis imperfecta, Marfan syndrome, and Ehlers-Danlos syndrome (EDS).

Potential Applications and Advantages

- Therapeutic for diseases arising from single gene disorders.
- Specific to the underlying disease unlike most current treatments.
- Therapeutic cells are recruited to the specific site of damage.
- Subsequent differentiation and localization of stem cells is therapeutic to the damaged tissue.

Development Status: Pre-clinical; however, patients with vascular type of the Ehlers-Danlos syndrome (VEDS) are being recruited for observational studies.

Inventors: Wilfried M. Briest and Mark I. Talan (NIA).

Patent Status: U.S. Provisional Application No. 61/233,537 filed 13 Aug 2009 (HHS Reference No. E–171–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *Fatima.Sayyid@nih.hhs.gov.*

HIV–1 Infection Detection Assay for Seroconverted HIV–1 Vaccine Recipients

Description of Invention: Available for licensing and commercial distribution is a serological test specifically designed to distinguish between antibodies generated in HIV vaccine recipients and those generated in a natural HIV infection. The method is useful in HIV vaccine development and clinical studies as it can readily detect early breakthrough infections in seroconverted vaccine recipients, thus providing the information required to determine vaccine efficacy. The test kit includes diagnostic peptide fragments derived from human immunodeficiency virus-1 (HIV–1). The peptide epitopes are primarily derived from the GAG-p6 and gp41 genes. These epitopes are broadly reactive with early sera from HIV infected individuals, but do not illicit protective antibodies, or immunologic cytotoxicity, and thus can readily be excluded from current and future HIV–1 vaccine candidates.

Applications

- Vaccine efficacy studies; Detection of early seroconversion in vaccine recipients.
- Distinguishing between healthy vaccine recipients and natural HIV infection.
- Blood bank screening.

Advantages: Cost effective method to determine vaccines efficacy in clinical studies.

Market: In spite of the more than twenty years of efforts to develop HIV vaccine, such vaccine does not yet exist. While treatment of HIV/AIDS with antiretroviral drugs can reduce viral load and extend life, this approach does not provide a true cure and cannot stop the HIV/AIDS pandemic. The medical community therefore fully recognizes the urgency to develop an effective vaccine for HIV/AIDS. In spite of the many challenges in the development of such vaccine (out of the 75 vaccine candidates that entered clinical trials over the years only 3 have reached the stage of large-scale efficacy trials and to date none have prove efficacious) the efforts in this area will continue to receive high priority by the public sector and high level of research funding. In order to make progress in this area, public sectors in many countries as well as not-for-profit NGOs have in recent years developed strategies and provided incentives to the private sector to continue with the efforts through the creation of public-private partnerships. Development of tools that can facilitate clinical trials, such as the present invention, may therefore be a good commercial opportunity, in particular in light of the potential market for HIV/AIDS vaccine. While the market for therapeutic drugs against HIV/AIDS across the seven major markets is now approaching $11.0 billion annually and growing at about 12.8% a year, the International AIDS Vaccine Initiative (IAVI) projects $2.5 billion to $5.5 billion in peak annual revenues of any new vaccine. This projection is based on peak demand of between 38 and 152 million courses (two doses per one course) depending on the vaccine profile. The projection also takes into consideration a tiered pricing and this projected revenue represents 5% to 13% of the total global vaccine market.

Inventors: Hana Golding and Surender Khurana (FDA).

Related Publications

1. S Khurana *et al.* Human immunodeficiency virus (HIV) vaccine trials: A novel assay for differential diagnosis of HIV infections in the face of vaccine-generated antibodies. J Virol. 2006 March;80(5): 2092–2099. [PubMed: 16474117].

2. S Khurana *et al.* Novel approach for differential diagnosis of HIV infections in the face of vaccine-generated antibodies: Utility for detection of diverse HIV–1 subtypes. J Acquir Immune Defic Syndr. 2006 Nov 1;43(3):304–312. [PubMed: 17019363].

3. S Khurana *et al.* HIV–SELECTEST EIA and rapid test: Ability to detect seroconversion following HIV–1 infection. J Clin Microbiol. 2009 Nov 11. Epub ahead of print. doi:10.1128/JCM.01573–09. [PubMed: 19906903].

Patent Status

- U.S. Provisional Application No. 60/607,579 filed 08 Sep 2004 (HHS Reference No. E–259–2004/0–US–01).
- U.S. Provisional Application No. 60/676,931 filed 03 May 2005 (HHS Reference No. E–259–2004/1–US–01).
- PCT Application No. PCT/US2005/031287, which published as WO/2007/018550 on 15 Feb 2007 (HHS Reference No. E–259–2004/2–PCT–01); and related applications: U.S. Patent Application No. 11/662,370 filed 02 Sep 2005, published 27 Jun 2007; Australia Patent Application No. 2005335203, published 04 Apr 2007; Canadian Patent Application No. 2579676; European Patent Application No. 2005858397, published 27 Jun 2007.
- U.S. Provisional Application No. 61,180,233 filed 21 May 2009 (HHS Reference No. E–259–2004/3–US–01).

Licensing Status: Available for licensing.

Licensing Contacts: Uri Reichman, Ph.D., M.B.A.; 301–435–4616; *UR7a@nih.gov;* or Michael Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov*.

Dated: January 21, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–1665 Filed 1–27–10; 8:45 am]

BILLING CODE 4140–01–P