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

Related Publications:


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 therapies 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. (UCI).


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 knock-out 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 (NIH).


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.nih.gov.


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

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.

Licensing Contact: Norbert Pontzer, J.D., Ph.D.; 301–435–5502; pontzer@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@niddcr.nih.gov for more information.


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

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

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

BILING CODE 4140–01–P
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.

Advantages
- 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).

Applications
- Treatment of radiation-induced oral mucositis.
- Prevention of radiation-induced oral mucositis.

Development Status: Pre-clinical.

Inventor: Changyu Zheng, Ph.D.; 301–435–5560; Zhengc@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 bradleyd@niddcr.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.

Applications
- Identification of specific mutations in ERBB4 for diagnostic purposes.
- Identification of specific mutations in ERBB4 for therapeutic purposes.

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

Market
- Identification of specific mutations in ERBB4 for diagnostic purposes.
- Identification of specific mutations in ERBB4 for therapeutic purposes.

Inventors: Yarden A. Samuels et al. (NHGRI).


Licensing Status: Available for licensing.

Chemogenomics 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.

Applications
- Identification of specific mutations in ERBB4 for diagnostic purposes.
- Identification of specific mutations in ERBB4 for therapeutic purposes.

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

Market
- Identification of specific mutations in ERBB4 for diagnostic purposes.
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Additionally, the risk of developingraft 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).


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


Patent Status

Licensing Status: Available for licensing.

Licensing Contacts: Uri Reichman, Ph.D., M.B.A.; 301–435–4616; UR7@nih.gov; or Michael Shmilovich, Esq.; 301–435–5019; shmilovm@mail.nih.gov.


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

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