identification (ID) number on your check, bank draft, or postal money order. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This U.S. Bank address is for courier delivery only.)

Please make sure that the FDA post office box number (P.O. Box 979107) is written on the check, bank draft, or postal money order.

Wire transfer payment may also be used. Please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee between $15.00 and $35.00. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Dept of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Dr., Rockville, MD, 20850.

Application fees can also be paid online with an electronic check (ACH). FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA Web site after the user fee ID number is generated.

The tax identification number of the Food and Drug Administration is 53–0196965.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2012 under the new fee schedule in August 2011. Payment will be due on October 1, 2011. FDA will issue invoices in November 2012 for any products and establishments subject to fees for FY 2012 that qualify for fee assessments after the August 2011 billing.

Dated: July 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–19332 Filed 7–29–11; 8:45 am]

BILLING CODE 4160–01–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.

Combination Cancer Therapy Using an IL13-Targeted Toxin and a Vaccine

Description of Technology: Typical cancer treatments such as chemotherapy, radiation therapy and surgical resection are non-specific processes that kill healthy cells as well as diseased cells, ultimately resulting in discomfort and undesirable side-effects for patients. In an effort to reduce the burden on cancer patients, a tremendous effort has been placed on developing ways to increase the specificity of cancer treatments. One way to increase specificity is to identify proteins which are present on the surface of cancer cells but absent on normal healthy cells, and use that protein as a target for delivering a therapeutic agent. Because the therapeutic agent only reaches the diseased cell, patients are less likely to experience non-specific side-effects, reducing their pain burden during treatment.

IL13-receptor-alpha-2 (IL13–Rα2) is a cell surface protein that is selectively expressed on certain diseased cells, including cancer cells. IL13–Rα2 binds to the cytokine IL13, suggesting that a therapeutic agent fused to IL13 can target and kill only those cancer cells which express IL13–Rα2. Our inventors previously constructed fusion proteins comprising (1) IL13 and (2) an active fragment of the bacterial toxin *Pseudomonas* exotoxin A (PE). These IL13–PE fusion proteins demonstrated the ability to selectively kill cancer cells that overexpressed IL13–Rα2, as well as other types of diseased cells (asthma, pulmonary fibrosis) which overexpressed IL13–Rα2. This suggested that IL13–PE fusion proteins were excellent candidates for new therapeutic agents.

The inventors recently sought methods to increase the effectiveness of these IL13–PE fusion proteins in the treatment of disease. This technology is directed to a combination therapy comprising (a) a DNA vaccine against IL13–Rα2 and (b) an IL13–PE fusion protein. By combining these therapeutic approaches it is possible to kill certain cell types that express IL13–Rα2 at high levels (such as cancer cells), making this combinatorial approach an attractive potential therapeutic.

Applications:

- Treatment of diseases associated with the increased expression of IL13–Rα2
- Relevant diseases include pulmonary fibrosis, asthma and cancers such as pancreatic cancer, glioblastoma multiforme and other head and neck cancers

Advantages:

- The DNA vaccine only affects cells where IL13–Rα2 expression is increased, limiting their effects to diseased cells
- IL13–PE fusion proteins also only kill cells that overexpress IL13–Rα2, allowing specific targeting of treatment
- Targeted treatment decreases non-specific killing of healthy, essential cells, resulting in fewer side-effects and healthier patients

Development Status: Preclinical stage of development.

Inventors: Puri *et al.* (FDA).

Patent Status: US provisional application 61/451,331 (HHS reference E–104–2011/0–US–01).

For more information, see:

- US Patents 5,614,191, 5,919,456 and 6,518,061 (HHS technology reference E–266–1994/0)
- US Patent Publication US 20040136959 A1 (HHS technology reference E–032–2000/0)
- US Patent 7,541,040 (HHS technology reference E–296–2001/0)

Licensing Status: Available for licensing.

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

Combination Cancer Therapy Using an IL13-Targeted Toxin and an HDAC Inhibitor

Description of Technology: Typical cancer treatments such as chemotherapy, radiation therapy and surgical resection are non-specific processes that kill healthy cells as well as diseased cells, ultimately resulting in discomfort and undesirable side-effects for patients. In an effort to reduce the burden on cancer patients, a tremendous effort has been placed on developing ways to increase the specificity of cancer treatments. One way to increase specificity is to identify proteins which are present on the surface of cancer cells but absent on normal healthy cells, and use that protein as a target for delivering a therapeutic agent. Because the therapeutic agent only reaches the diseased cell, patients are less likely to experience non-specific side-effects, reducing their pain burden during treatment.

IL13-receptor-alpha-2 (IL13–Rα2) is a cell surface protein that is selectively expressed on certain diseased cells, including cancer cells. IL13–Rα2 binds to the cytokine IL13, suggesting that a therapeutic agent fused to IL13 can target and kill only those cancer cells which express IL13–Rα2. Our inventors previously constructed fusion proteins comprising (1) IL13 and (2) an active fragment of the bacterial toxin *Pseudomonas* exotoxin A (PE). These IL13–PE fusion proteins demonstrated the ability to selectively kill cancer cells that overexpressed IL13–Rα2, as well as other types of diseased cells (asthma, pulmonary fibrosis) which overexpressed IL13–Rα2. This suggested that IL13–PE fusion proteins were excellent candidates for new therapeutic agents.

In an effort to increase the effectiveness of these IL13–PE fusion proteins, the inventors sought ways to increase the expression of IL13–Rα2 on cancer cells, thereby increasing the rate at which the therapeutic agent could kill the diseased cell. Histone deacetylase (HDAC) inhibitors have been employed as anti-cancer agents for several years, and a number of HDAC inhibitors are currently in clinical trials. Although the exact mechanism by which HDAC inhibitors function is unclear, it is believed that the ability of these molecules to increase the expression of anti-cancer genes is behind their therapeutic effect.

This invention concerns a means of improving specific cancer therapy through the combination of (a) IL13–PE fusion proteins and (b) HDAC inhibitors. The inventors surprisingly found that the expression of IL13–Rα2 increased in several types of pancreatic cancer cells in response to HDAC inhibitors, whereas normal, healthy cells did not experience such an increase in IL13–Rα2 expression. The use of IL13–PE fusion proteins in combination with HDAC inhibitors improved specific killing of pancreatic cancer cells relative to the use of IL13–PE fusion proteins in the absence of the HDAC inhibitors. This suggested that the use of IL13–PE fusion proteins along with HDAC inhibitors was a strong candidate combinatorial therapeutic for the treatment of various cancers (e.g., pancreatic, glioblastoma multiforme) and other diseases characterized by overexpression of IL13–Rα2 (e.g., asthma, pulmonary fibrosis).

Applications:

- Treatment of diseases associated with the increased expression of IL13–Rα2
- Relevant diseases include pulmonary fibrosis, asthma and cancers such as pancreatic cancer, glioblastoma multiforme and other head and neck cancers

Advantages:

- HDAC inhibitors only increased IL13–Rα2 expression in diseased cells, leaving normal healthy cells unaltered
- IL13–PE fusion proteins only kill cells that overexpress IL13–Rα2, allowing specific targeting of treatment
- Targeted treatment decreases non-specific killing of healthy, essential cells, resulting in fewer side-effects and healthier patients

Development Status: Preclinical stage of development

Inventors: Puri *et al.* (FDA)

Patent Status: US provisional application 61/494,779 (HHS reference E–107–2011/0–US–01)

For more information, see:

- US Patents 5,614,191, 5,919,456 and 6,518,061 (HHS technology reference E–266–1994/0)
- US Patent Publication US 20040136959 A1 (HHS technology reference E–032–2000/0)
- US Patent 7,541,040 (HHS technology reference E–296–2001/0)

Licensing Status: Available for licensing

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

Dated: July 26, 2011.

Richard U. Rodriguez,

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

[FR Doc. 2011–19378 Filed 7–29–11; 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.

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Methods and Software for the Quantitative Assessment of Vasculature in Allantois and Retina Explants

Description of Technology: The invention relates to methods and software that can facilitate and improve quantification, accuracy and standardization in the assessment of vasculature in angiogenesis assays such as in the allantois explants and the retina explants assays. The software of this invention can aid in the analysis of images resulting from these assays and thus enhance the accuracy and effectiveness of research in the area of angiogenesis. This in turn will lead to enhanced progress in the development of medical methods and drugs to treat diseases related to angiogenesis such as cancer, macular degeneration, and some pregnancy disorders.

Applications: The software can be integrated with a variety of imaging systems used in conjunction with angiogenesis assays to enhance the assessment and the quality of research in the area of angiogenesis.

Advantages:

- The method and software of the invention will make analysis of angiogenesis assays more accurate, better standardized, and less