

antiandrogens, the new small molecules induce androgen receptor degradation and cell death in prostate cancer cells. Further, these compounds and methods can also induce degradation of other steroid hormone receptors demonstrating the possibility of treating a wider range of cancers.

**Potential Commercial Applications:**

- Series of steroid receptor compounds that cause cancer cell death
- Method of using the compounds in cancer treatment

**Competitive Advantages:**

- First small molecule antiandrogen treatment
- Causes cell death, not just loss of function
- Potential to treat other cancers through degradation of other steroid hormone receptors

**Development Stage:** *In vitro* data available.

**Inventors:** Jane B. Trepel, Yeong Sang Kim, Sunmin Lee, Vineet Kumar, and Sanjay V. Malhotra (NCI).

**Intellectual Property:** HHS Reference No. E-015-2011/0—U.S. Patent Application No. 61/497,129 filed 15 Jun 2011.

**Licensing Contact:** Whitney Hastings; (301) 451-7337; [hastingw@mail.nih.gov](mailto:hastingw@mail.nih.gov).

**Collaborative Research Opportunity:** The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Small Molecules for the Treatment of Prostate Cancer. For collaboration opportunities, please contact John Hewes, PhD at [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) or (301) 496-0477.

Dated: October 21, 2011.

**Richard U. Rodriguez,**

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

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**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.

#### Protease Deficient *Bacillus anthracis* With Improved Recombinant Protein Yield Capabilities

**Description of Technology:** Species of *Bacillus*, such as *Bacillus anthracis*, *Bacillus cereus*, and *Bacillus subtilis*, are attractive microorganisms for recombinant protein production in view of their fast growth rate, high yield, and ability to secrete produced products directly into the medium. *Bacillus anthracis* is also attractive in view of its ability to produce anthrax toxin and ability to fold proteins correctly. This application claims a *B. anthracis* strain in which more than one secreted protease is inactivated by genetic modification. Such a protease-deficient *B. anthracis* has an improved ability to produce recombinant secreted proteins compared to other bacteria, particularly other *Bacillus*. Improvements include production of intact (i.e., mature full-length) proteins, often at high yield.

**Potential Commercial Applications:**

- Vaccine production
- Recombinant protein production
- *B. anthracis* vaccine production

**Competitive Advantages:**

- Highly efficient production of recombinant proteins
- Low cost production of recombinant proteins

**Development Stage:**

- Early-stage
- *In vitro* data available

**Inventors:** Andrei Pomerantsev and Stephen Leppla (NIAID).

**Publication:** Pomerantsev A, *et al.* A *Bacillus anthracis* strain deleted for six proteases serves as an effective host for production of recombinant proteins. *Protein Expr Purif.* 2011 Nov;80(1):80-90. [PMID 21827967].

**Intellectual Property:**

• HHS Reference No. E-202-2011/0—U.S. Provisional Application No. 61/514,384 filed 02 Aug 2011

• HHS Reference No. E-202-2011/1—U.S. Provisional Application No. 61/521,617 filed 09 Aug 2011

**Licensing Contact:** Peter Soukas, J.D.; (301) 435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

**Collaborative Research Opportunity:**

The NIAID is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize *B. anthracis* vaccines, *B. anthracis* protein production. For collaboration opportunities, please contact Charles Rainwater at (301) 435-8617.

#### Parvovirus B19 Codon Optimized Structural Proteins for Vaccine and Diagnostic Applications

**Description of Technology:** Parvovirus B19 (B19V) is the only known pathogenic human parvovirus. Infection by this viral pathogen can cause transient aplastic crisis in individuals with high red cell turnover, pure red cell aplasia in immunosuppressed patients, and hydrops fetalis during pregnancy. In children, B19V most commonly causes erythema infectiosum, or fifth's disease. Infection can also cause arthropathy and arthralgia. The virus is very erythrotropic, targeting human erythroid (red blood) progenitors found in the blood, bone marrow, and fetal liver. Currently, there are no approved vaccines or antiviral drugs for the treatment or prevention of B19V infection.

The subject technology is a series of plasmid constructs with codon optimized B19 viral capsid genes (VP1 and VP2) that can be expressed in mammalian cells. Transfection of vectors encoding these optimized VP1 and VP2 genes into different mammalian cell lines, including 293, Cos7, and HeLa cells produce virus-like particles (VLPs). The vectors include bicistronic plasmids expressing the VP1 and VP2 proteins at different ratios to produce B19V VLPs with optimal antigenicity for vaccine applications. This technology can also be used for diagnostic applications and development of a viral packaging system for producing infectious B19V virus.

**Applications:**

- VLPs based vaccines for the prevention and/or treatment of B19V infection
- DNA based vaccines for the prevention and/or treatment of B19V infection
- B19V diagnostics
- Viral packaging system

**Advantages:**

- Codon optimized VP1 and VP2 genes for better expression in mammalian cell lines

- Expression of B19V VLPs from “nonpermissive” cell lines

*Development Stage:* In vitro data available.

*Inventors:* Ning Zhi, Sachiko Kajigaya, and Neal S. Young (NHLBI).

*Patent Status:* HHS Reference No. E-011-2010/0—PCT Application No. PCT/US2011/024199 filed 09 Feb 2011.

*Licensing Contact:* Kevin W. Chang, Ph.D.; (301) 435-5018; [changke@mail.nih.gov](mailto:changke@mail.nih.gov).

*Collaborative Research Opportunity:* The National Heart Lung and Blood Institute, Hematology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the subject technology. Please contact Cecilia Pazman, Ph.D., at [pazmance@mail.nih.gov](mailto:pazmance@mail.nih.gov) for more information.

Dated: October 21, 2011.

**Richard U. Rodriguez,**

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

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Licensing and Collaborative Research Opportunity for PANVAC—Cancer Vaccine for the Prevention and Treatment of Colorectal Cancer

**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 contacting Sabarni Chatterjee at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852; telephone: (301) 435-

5587; email [chatterjeesa@mail.nih.gov](mailto:chatterjeesa@mail.nih.gov). A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Inquiries related to Collaborative Research Opportunities may be directed to Michael Pollack at the Technology Transfer Center, National Cancer Institute, 6120 Executive Boulevard, Suite 450, Rockville, MD 20852; telephone: (301) 435-3118; email [pollackm@mail.nih.gov](mailto:pollackm@mail.nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Technology Summary

PANVAC is a pox-vector-based cancer vaccine in clinical stage development with high potential for leading to a new therapeutic approach in the prevention and treatment of colorectal cancer. A combination of carcinoembryonic antigen (CEA) and pan-carcinoma antigen MUC-1, and TRICOM, PANVAC has been used with promising results in treating metastatic colorectal cancer.

In a recent multicenter phase II clinical trial reported at ASCO 2011, improved survival was observed among patients vaccinated with PANVAC following resection of colorectal cancer metastases; at a median follow up of forty (40) months, the survival rate of vaccinated patients clearly exceeding that of the unvaccinated contemporary control population. T-cell responses to CEA were also observed in vaccinated patients.

##### Competitive Advantage of Our Technology

- The technology is in clinical stage, supported by clinical results and numerous publications.
- TRICOM, contained in pox vectors have been evaluated in prime (V)/boost (F) regimens in preclinical models and in several clinical trials in patients with metastatic colorectal cancer.
- Phase I and Phase II clinical data are available (to qualified licensees) for poxvirus recombinants containing transgenes for TRICOM, CEA-TRICOM, and PANVAC. Further clinical studies are ongoing.
- Given the relatively more advanced stage of development of this technology, fewer validation studies are required compared to other immunotherapy related technologies.

##### Technology Description

Cancer immunotherapy is an approach where tumor associated antigens (TAAs), which are primarily expressed in human tumor cells, and not expressed or minimally expressed in normal tissues, are employed to generate a tumor-specific immune response. Specifically, these antigens

serve as targets for the host immune system and elicit responses that results in tumor destruction. The initiation of an effective T-cell immune response to antigens requires two signals. The first one is antigen-specific via the peptide/major histocompatibility complex and the second or “costimulatory” signal is required for cytokine production, proliferation, and other aspects of T-cell activation.

The PANVAC technology employs avirulent poxviruses to present a combination of tumor-associated antigens (TAAs) and costimulatory molecules to activate T-cells and break the immune systems tolerance towards cancer cells. This is performed using recombinant poxvirus DNA vectors that encode both T-cell costimulatory molecules and TAAs. The combination of the costimulatory molecules B7.1, ICAM-1 and LFA-3, is known as TRICOM. Recombinant poxviral vaccines (vaccinia (V) and fowlpox (F) containing TRICOM have been evaluated in prime (V)/boost (F) regimens in preclinical models and in several clinical trials in patients with metastatic colorectal cancer. Additionally, PANVAC has shown promising survival results in treating patients with metastatic colorectal cancer.

Furthermore, recombinant poxviral TRICOM based vaccines can also be employed for the prevention and/or therapy of colorectal cancer containing a range of other TAAs such as the T-box transcription factor Brachyury.

##### Market

With the identification of molecular targets associated with cancer, the focus of drug development has shifted from broadly acting cytotoxic drugs to targeted therapeutics in the hope of finding drugs that selectively kill cancer cells and do not harm normal cells. Historically, because the expertise of pharmaceutical companies has been in the domain of small molecule therapeutics, several compounds have been developed that inhibit the abnormal biochemical activity of cancer cells. This approach has been successful to an extent as illustrated by the kinase inhibitors and EGFR inhibitors. However, as for chemotherapeutics, cancer cells frequently acquire drug resistance to targeted small-molecule therapeutics rendering them ineffective in the long run. In addition, these small-molecules produce adverse side effects which can prevent the administration of the maximum effective dose. An alternative approach to overcome these problems relies on the use of biologics such as antibodies and vaccines.