

- 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.

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 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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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. 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.

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.

The biotechnology industry has principally focused on an immunotherapy approach using monoclonal antibodies (mAb) to enlist the help of the patient's own immune system. This approach has successfully led to several FDA approved and marketed mAbs. Typically, cancer cells are less susceptible to acquiring resistance to antibodies; however, as seen for trastuzumab, resistance can occur. Another limitation of mAbs is that they activate only part of the immune system and do not produce future immunity against the cancer. More recently, cancer vaccines are being developed as an addition to the immunotherapy approach. It is expected that activating the cells of the immune system should be effective in killing cancer cells with the added benefit that it would lead to a sustained surveillance by the patient's own body that prevents the tumor from reemerging in the future.

Vaccines have been very successful in the prevention of infectious diseases, and are now being evaluated for the treatment of cancer. The development of cancer vaccines could result in a paradigm shift in the treatment and clinical management of cancer. Recently, a cancer vaccine PROVENGE® (Sipuleucel-T) was approved by the FDA for the treatment of metastatic prostate cancer. The development of the TRICOM-based "off the shelf" technology using costimulatory vaccines is designed to magnify the immune response against cancer cells and lead to prolonged cancer immunity.

PANVAC has much potential for becoming a therapeutically effective cancer vaccine for colorectal cancer. It has demonstrated evidence of patient benefit in several Phase I and II clinical studies demonstrating a high safety profile and is a good candidate for initiating pivotal efficacy studies. Recently, very encouraging results were announced for PROSTVAC™ (prostate cancer vaccine), based on the same TRICOM technology platform as PANVAC, which further validates this technology platform. PANVAC is a decidedly mature technology that holds promise to transform the treatment of colorectal cancer.

Patent Estate

The portfolio includes the following issued patents and pending patent applications:

1. U.S. Patent No. 6,756,038 issued June, 29 2004 as well as issued and pending foreign counterparts [HHS Ref. No. E-099-1996/0-US-07];
2. U.S. Patent No. 7,723,096 issued May 25, 2010 as well as continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-099-1996/0-US-08];
3. Europe Patent No. 1017810 [HHS Ref. No. E-099-1996/0-EP-05], and all European contracting states in which this patent is validated;
4. Europe Patent Application No. 04011673.3 (now EP Patent No. 1447414) [HHS Ref. No. E-099-1996/0-EP-17], and all European contracting states in which this patent is validated, Japan Patent Application No. 2000-516030 (now JP Patent No. 4291508) [HHS Ref. No. E-099-1996/0-JP-06], and all continuations and divisional applications claiming priority to this application;
5. Australia Patent No. 745863 [HHS Ref. No. E-099-1996/0-AU-03], and all continuations and divisional applications claiming priority to this application;
6. Canada Patent No. 2308127 [HHS Ref. No. E-099-1996/0-CA-04], and all continuations and divisional applications claiming priority to this application;
7. U.S. Patent No. 5,698,530 issued December 6, 1997 as well as issued and pending foreign counterparts [HHS Ref. No. E-200-1990/1-US-02];
8. Australian Patent No. 674492 issued April 22, 1997 [HHS Ref. No. E-200-1990/2-AU-02]; Europe Patent No. 0584266 issued September 3, 2003 [HHS Ref. No. E-200-1990/2-EP-04]; Japan Patent No. 3399943 issued February 21, 2003 [HHS Ref. No. E-200-1990/2-JP-05]; and Canada Patent No. 2102623 issued April 22, 2003 [HHS Ref. No. E-200-1990/2-CA-03];
9. U.S. Patent No. 6,001,349 issued December, 14, 1999 as well as issued and pending foreign counterparts [HHS Ref. No. E-200-1990/3-US-01];
10. U.S. Patent Application No. 10/579,025 filed May 11, 2006 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-087-2005/0-US-03];
11. U.S. Patent Application No. 10/579,007 filed May 11, 2006 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-088-2005/0-US-03];
12. U.S. Patent No. 7,118,738 issued October 10, 2006 as well as all continuations and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-154-1998/0-US-07];
13. U.S. Patent Application Nos. 08/686,280 filed July 25, 1996 as well as all issued and pending foreign counterparts [HHS Ref. No. E-259-1994/3-US-01];
14. U.S. Patent No. 7,410,644 issued August 12, 2008 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-259-1994/3-US-08];
15. U.S. Patent Nos. 6,893,869, 6,548,068 and 6,045,802 issued May 17, 2005, April 15, 2003 and April 4, 2000 respectively, as well as issued and pending foreign counterparts [HHS Ref. Nos. E-260-1994/1-US-03, US-02, US-01]; U.S. Patent No. 7,368,116 issued May 6, 2008 and U.S. Patent Application No. 12/112,819, as well as all continuation and divisional applications [HHS Ref. Nos. E-260-1994/1-US-04 and US-05];
16. Europe Patent Application No. 00102998.2 filed October 2, 1995, Europe Patent No. 0784483 issued November 29, 2001, Europe Patent Application No. 09013495.8 filed October 26, 2009, as well as all continuation, and divisional applications [HHS Ref. Nos. E-260-1994/2-EP-15, EP-16 and EP-27]; Japan Patent Application No. 512100/96 filed October 2, 1995; Japan Patent No. 4078319 issued February 8, 2008 [HHS Ref. No. E-260-1994/2-JP-25]; and Japan Patent No. 4160612 issued July 25, 2008, as well as all continuation and divisional applications; [HHS Ref. No. E-260-1994/2-JP-21, JP-25 and JP-26]; Australia Patent No. 688606 issued July 2, 1998 [HHS Ref. No. E-260-1994/2-AU-11]; Canada Patent No. 2201587 issued June 25, 2002 [HHS Ref. No. E-260-1994/2-CA-12];
17. Canada Patent Application No. 2,412,050 filed June 15, 2001 [HHS Ref. No. E-187-2000/0-CA-05]; Australia Patent No. 2001268452 issued November 30, 2006 [HHS Ref. No. E-187-2000/0-AU-06]; Japan Patent Application No. 2002-510097 filed June 15, 2001 [HHS Ref. No. E-187-2000/0-JP-07]; Hong Kong Patent Application No. 03105975.5 filed June 15, 2001 [HHS Ref. No. E-187-2000/0-HK-08];
18. U.S. Patent Application No. 12/280,534 filed February 21, 2007, [HHS Ref. No. E-104-2006/0-US-06]; Australia Patent Application No. 2007221255 filed February 21, 2007 [HHS Ref. No. E-104-2006/0-AU-03]; Europe Patent Application No. 07751371.1 filed February 21,

- 2007, [HHS Ref. No. E-104-2006/0-EP-05]; Canada Patent Application No. 2642994 filed February 21, 2007 [HHS Ref. No. E-104-2006/0-CA-04];
19. U.S. Patent Application No. 12/528,796 filed August 26, 2009 [HHS Ref. No. E-074-2007/0-US-07]; Australia Patent Application No. 2008221383 filed February 27, 2008 [HHS Ref. No. E-074-2007/0-AU-03]; Europe Patent Application No. 08743578.0 filed February 27, 2008 [HHS Ref. No. E-074-2007/0-EP-05]; Canada Patent Application No. 2,678,404 filed February 27, 2008 [HHS Ref. No. E-074-2007/0-CA-04]; Japan Patent Application No. 2009-551830 filed February 27, 2008 [HHS Ref. No. E-074-2007/0-JP-06];
20. U.S. Patent No. 6,969,609 issued November 29, 2005; U.S. Patent No. 7,211,432 issued May 1, 2007; U.S. Patent Application No. 11/723,666 filed March 21, 2007; as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-256-1998/0, 1];
21. U.S. Patent Application Nos. 60/448,591 and 10/543,944 filed February 20, 2003 and February 20, 2004 respectively, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-028-2007/0];
22. U.S. Patent No. 6,699,475 issued March 2, 2004, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-134-2007/0];
23. U.S. Patent No. 5,093,258 issued March 3, 1992, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-135-2007/0];
24. U.S. Patent Application No. 07/205,189 filed June 10, 1988, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-136-2007/0];
25. U.S. Patent Application No. 60/625,321 filed November 5, 2004, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-138-2007/0];
26. U.S. Patent Application No. 60/678,329 filed May 5, 2005, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-139-2007/0]; and

27. U.S. Patent Application No. 07/340,052 filed April 18, 1989, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-147-2007/0].

Note that some of the patent estate above is available for non-exclusive licensing only.

Cooperative Research and Development Agreement (CRADA) Opportunities

A CRADA partner for the further codevelopment of this technology specifically in colorectal cancer is currently being sought by the Laboratory of Tumor Immunology and Biology, Center for Cancer Research, NCI. The CRADA partner will (a) generate and characterize recombinant poxviruses expressing specific tumor-associated antigens, cytokines, and/or T-cell costimulatory factors, (b) analyze the recombinant poxviruses containing these genes with respect to appropriate expression of the encoded gene product(s), (c) supply adequate amounts of recombinant virus stocks for preclinical testing, (d) manufacture and test selected recombinant viruses for use in human clinical trials for colorectal cancer, (e) submit Drug Master Files detailing the development, manufacture, and testing of live recombinant vaccines to support the NCI-sponsored IND and/or company-sponsored IND, (f) supply adequate amounts of clinical grade recombinant poxvirus vaccines for clinical trials conducted at the NCI Center for Cancer Research (CCR), and (g) provide adequate amounts of vaccines for extramural clinical trials, if agreed upon by the parties, and conduct clinical trials under company-sponsored or NCI-sponsored INDs. NCI will (a) provide genes of tumor-associated antigens, cytokines and other immunostimulatory molecules for incorporation into poxvirus vectors, (b) evaluate recombinant vectors in preclinical models alone and in combination therapies, and (c) conduct clinical trials for colorectal cancer of recombinant vaccines alone and in combination therapies.

Next Step

Licensing and CRADA

Licensing and collaborative research opportunities are available. If you are interested in licensing and/or CRADA opportunities, please contact call Sabarni Chatterjee at (301) 435-5587 or email chatterjeesa@mail.nih.gov (for licensing) and Michael Pollack at (301) 435-3118 or email pollackm@mail.nih.gov (for CRADAs).

Dated: October 21, 2011.

Richard U. Rodriguez,

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

[FR Doc. 2011-27859 Filed 10-26-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Pilot Clinical Trial.

Date: November 4, 2011.

Time: 5 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 435-6033, rajarams@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 21, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-27871 Filed 10-26-11; 8:45 am]

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