42 CFR Citation and purpose	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hours
Total	1,621		2,418		2,186

* Average.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 *and* e-mail her a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received within 60 days of this notice.

Dated: October 8, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–24940 Filed 10–15–09; 8:45 am]

BILLING CODE 4162–20–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.

B-cell Surface Reactive Antibodies for the Treatment of B–Cell Chronic Lymphocytic Leukemia

Description of Technology: B-cell chronic lymphocytic leukemia (B–CLL) is a cancer characterized by a progressive accumulation of functionally incompetent lymphocytes. Despite high morbidity and mortality, the only available potential cure is allogeneic hematopoietic stem cell transplantation (alloHSCST). However, there is less than a 50% chance of finding a matching bone marrow or blood donor for B–CLL patients. Other clinically tested targeted therapies such as rituximab and alemtuzumab target both malignant and normal B cells, resulting in immunosuppression.

Available for licensing are fully human monoclonal antibodies that were selected from the first human post-alloHSCT antibody library. The library was generated from a time point after transplantation at which antibodies to B–CLL cell surface antigens peaked, thus indicating its therapeutic value. Utilizing phage display, the investigators generated a panel of fully human monoclonal antibodies that strongly bind to the same epitope on a B–CLL cell surface antigen. Weaker binding to normal B cells, but not to other lymphocytes, was observed. These fully human monoclonal antibodies provide readily available treatment that selectively targets malignant B cells.

Applications:

- B-cell chronic lymphocytic leukemia therapeutics.
- Method to inhibit the growth of malignant B-cells.
- Method to detect B-cell tumors.

Advantages:

- Selective targeting of malignant B-cell surface antigens that are minimally non-damaging to non-diseased cells.
- Readily available therapeutics without the need for bone marrow or blood transplantation.

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

Market:

- Monoclonal antibody market has the potential to reach $30.3 billion in 2010 largely driven by technological evolution from chimeric and humanized to fully human antibodies.
- In the U.S., there is annual incidence of an estimated 15,000 newly diagnosed cases of B–CLL and the disease is responsible for an estimated 4,500 deaths.

Inventors: Christoph Rader *et al.* (NCI)

Publication: S Baskar, JM Suschak, I Samija, R Srinivasan, RW Childs, SZ Pavletic, MR Bishop, C Rader. A human monoclonal antibody drug and target discovery platform for B-cell chronic lymphocytic leukemia based on allogeneic hematopoietic stem cell transplantation and phage display. Blood, in press. Epub ahead of print, 2009 Aug 10.

Patent Status: U.S. Provisional Application No. 61/178,688 filed 15 May 2009 (HHS Reference No. E–163–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Experimental Transplantation and Immunology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize fully human monoclonal antibodies selected from post-alloHSCT antibody libraries. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

CXCR4 and CCR10 Expressing Cells: Useful for the Study of Cancer Cell Survival and Metastasis

Description of Technology: The chemokine receptor CXCR4 functions in normal cells, but has been shown to be the most common chemokine receptor expressed on cancer cells, including melanoma, colon, breast, and lung cancers. It plays roles in angiogenesis and cancer cell survival as well as metastasis. CCR10 has also been shown to be expressed by melanoma cells. Like CXCR4, expression of CCR10 can enhance cancer cell survival and block immune recognition of cancer cells. Antagonists of CXCR4 and CCR10, under various conditions, have decreased metastasis or prevented tumor formation after implantation of cancer cells in mice.

These cell lines are based on the widely used B16 murine melanoma cell line. The cell lines were transduced with retroviral vectors encoding cDNA for either CXCR4 or CCR10 under control of a TET-dependent promoter. Both lines achieve greater than 10 fold induction of the respective genes (proteins), which has been confirmed by surface antibody staining using flow cytometry. These cell lines are ideally suited for studying the effect of these chemokine receptors in tumor growth or metastasis. They are also useful for

developing a mouse model for studying the effect of down-regulating these receptors specifically in melanoma cells. This would mimic the effect of antagonists without the confounding effects of systemically inhibiting CXCR4 or CCR10. By either adding or removing dietary administered doxycycline, receptor expression can be regulated to assess the role of these two receptors in a variety of cancer-related assays.

Applications:

• Study the effect of chemokine receptors in tumor growth or metastasis.

• Test CXCR4 and CCR10 antagonists in preclinical studies.

• Develop B16 melanoma mouse model mimicking the effect of chemokine receptor antagonists.

Advantages:

• Ability to regulate *in vitro* and *in vivo* expression of the chemokine receptor.

• Ability to investigate the *in vivo* role in cancer cells of doxycycline control of chemokine receptor expression.

Development Status: The technology is currently in the preclinical stage of development.

Market: Cancer is the second leading cause of death in the U.S. and it is estimated that more than 1 million Americans develop cancer in a year.

Inventors: Sam T. Hwang (NCI).

Publication: T Kakinuma, ST Hwang. Chemokines, chemokine receptors, and cancer metastasis. J Leukoc Biol. 2006 Apr;79(4):639–651.

Patent Status: HHS Reference No. E–345–2008/0—Research Material. Patent protection is not being sought for either technology.

Licensing Status: Available for non-exclusive licensing under a Biological Materials License Agreement.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov.*

Identification of Persons Likely To Benefit From Statin Mediated Cancer Prevention by Pharmacogenetics

Description of Technology: Inhibitors of 3-hydroxy-3-methylglutaryl (HMG) coenzyme A reductase (statins) are a class of well-tolerated compounds that are the most widely used cholesterol-lowering drugs in the United States. Reduced cancer risk among statin users has also been observed as a secondary outcome in randomized controlled clinical trials evaluating effects of statins on cardiovascular outcomes. However the observed cancer risk reduction varied with different clinical studies. Thus there is a need to identify individuals who would benefit from treatment with statins.

The current invention describes a pharmacogenetic method to identify candidates who are most likely to benefit from treatment with statins to reduce cancer risk, and consequently minimizing any unnecessary cost and side effects in individuals who do not benefit. Specifically, we discovered that an HMGCR genetic variant rs12654264 is associated with significantly lower colorectal cancer risk, with most of the benefit seen in HMGCoA reductase inhibitor (statin) users. We also discovered that this same HMGCR genetic variant is associated with significantly higher serum cholesterol levels in Israeli colorectal cancer patients. The same HMGCR genetic variant has also been associated with significantly higher serum cholesterol levels in two independent groups of individuals of mixed European descent [*http://www.broad.mit.edu/diabetes/scandinavs/index.html* and N Engl J Med.2008 March 20;358(12):1240–1249 (*http://www.ncbi.nlm.nih.gov/pubmed/18354102?dopt*)]. These data suggest that the same genetic variant modifies cholesterol metabolism in a manner that affects both colorectal cancer risk and cardiovascular risk.

Applications and Market:

• Statins account for approximately 80% of the cholesterol-lowering drugs prescribed in the United States, and six statins are currently available on the U.S. market. Reduced cancer risk is also associated with statin use. This invention provides a method to indentify individuals who are most likely to benefit from cancer chemopreventive treatment with statins.

• Pharmacogenetic markers can be developed to identify patient population that can be benefit from statins, therefore expands the markets of stains.

Development Status: The inventors have discovered several novel genetic variants of HMG coenzyme A reductase gene, and are further investigating the functional significance of the variants in vitro.

Inventors: Levy Kopelovich (NCI) *et al.*

Patent Status: PCT Application No. PCT/US2008/082359 filed 04 Nov 2008, which published as WO 2009/061734 on 14 May 2009 (HHS Reference No. E–328–2007/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov.*

Dated: October 7, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–24877 Filed 10–15–09; 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.

Biological/Research Material for H1N1 Influenza Virus Vaccine Research

Description of Technology: Offered for licensing is a recombinant attenuated vaccinia virus, MVA, that expresses the haemagglutinin (HA) and nucleoprotein (NP) of influenza virus A/PR/8/34 (H1N1). The virus has been shown to stimulate protective immunity to influenza virus in mice.

The materials can be used for research purposes and in particular in the area of influenza virus vaccines.

The related publications listed below demonstrate the usefulness of this biological material in influenza virus vaccine research.

Applications: Research reagents useful in research and development in the area of H1N1 Influenza virus vaccines.

Development Status: Fully developed. The usefulness of the materials has been shown in Dr. Moss' laboratory.