Dated: June 13, 2007.

Steven M. Ferguson,

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; 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.

NUP98–HOXD13 Transgenic Mice

Description of Technology: Myelodysplastic syndrome (MDS) is collection of closely related blood diseases that arise in the bone marrow characterized by anemia, neutropenia, and thrombocytopenia resulting from hematopoietic stem cell disorders. A variety of genetic aberrations have been associated with MDS, including chromosomal translocations of the NUP98 gene. The only current curative therapy for MDS is allogeneic bone marrow transplant. Without bone marrow transplant, patients either die of progressive pancytopenia or following transformation of MDS to acute myeloid leukemia. Progress in understanding and treating MDS has been hampered by a lack of an animal model that accurately recapitulates all of the features of human MDS. Utilizing a NUP98-HOXD13 (hereafter NHD13) fusion gene, a mouse model was developed to elucidate the biology of MDS. Genetically engineered mice that express an NHD13 transgene display all of the phenotypic features of MDS including peripheral blood cytopenia, bone marrow dysplasia, and transformation to acute leukemia. These mice provide an accurate preclinical model for MDS.

Applications: Model to study MDS and evaluate MDS therapy.

Market: 15,000–20,000 new cases of MDS are diagnosed in the U.S.; 80–90% of patients are older than 60 years old.

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

Inventors: Peter D. Aplan *et al.* (NCI).

Publications:

1. YW Lin *et al.* Notch1 mutations are important for leukemic transformation in murine models of precursor-T leukemia/lymphoma. Blood. 2006 Mar 15;107(6):2540–2543.

2. YW Lin *et al.*, NUP98-HOXD13 transgenic mice develop a highly penetrant, severe myelodysplastic syndrome that progresses to acute leukemia. Blood. 2005 Jul 1;106(1):287–295.

Patent Status: HHS Reference No. E–071–2007/0—Research Tool.

Licensing Status: Available for non-exclusive licensing.

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

Collaborative Research Opportunity: The Leukemia Biology Section, Genetics Branch, National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the NHD13 mouse model. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Identification of Ovarian Cancer Tumor Markers and Therapeutic Agents

Description of Technology: Germline mutations of BRCA1 and BRCA2 tumor suppressor genes are responsible for 5%–10% of all epithelial ovarian cancers. However, little is known about the molecular mechanisms involved in BRCA1 and/or BRCA2 mutation-associated (termed BRCA-linked) ovarian carcinogenesis. To elucidate their pathways, microarrays were used to compare gene expression patterns in ovarian cancers associated with BRCA1 or BRCA2 mutations with gene expression patterns in sporadic epithelial ovarian cancers to identify patterns common to both hereditary and sporadic tumors. As a result of this analysis, genes that are upregulated in ovarian cancer were identified. Approximately two-thirds of the sequences identified were previously known genes, while approximately one-third were expressed sequence tags, representing sequences that are cloned and identified but not yet characterized. Eighty-three genes were over-expressed in 50% of all tumors and these over-expressed sequences may be used as markers for ovarian cancer and/or targets for therapy.

Applications: Method to diagnose ovarian cancer; Method to treat ovarian cancer with therapeutics that target ovarian biomarkers; Ovarian cancer therapeutics that inhibit ovarian cancer markers such as siRNA.

Market: Estimated 180,000 new cases of breast cancer in the U.S. in 2007; Estimated 41,000 deaths due to breast cancer in the U.S. in 2007.

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

Inventors: Amir Jazaeri (NCI), Edison T. Liu (NCI), *et al.*

Publications:

1. AA Jazaeri *et al.* BRCA1-mediated repression of select X chromosome genes. J Transl Med. 2004 Sep 21;2(1):32.

2. AA Jazaeri *et al.* Molecular determinants of tumor differentiation in papillary serous ovarian carcinoma. Mol Carcinog. 2003 Feb;36(2):53–59.

3. AA Jazaeri *et al.* Gene expression profiles of BRCA1-linked, BRCA2-linked, and sporadic ovarian cancers. J Natl Cancer Inst. 2002 Jul 3;94(13):990–1000.

Patent Status: U.S. Provisional Application No. 60/357,031 filed 13 Feb 2002 (HHS Reference No. E–310–2001/0–US–01); PCT Patent Application No. PCT/US2003/046888 filed 13 Feb 2003 (HHS Reference No. E–310–2001/0–PCT–02); U.S. Patent Application No. 10/505,680 filed 12 Aug 2004 (HHS Reference No. E–310–2001/0–US–03).

Licensing Status: Available for exclusive or non-exclusive licensing.

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

Tumor Markers in Ovarian Cancer

Description of Technology: Ovarian cancer is one of the most common forms of neoplasia in women. Although advanced ovarian cancer has only a 20–30% survival rate, an estimated 90% of cases are effectively treated when detected early. However, few symptoms are associated with early ovarian cancer, and approximately 25% of ovarian cancer cases are diagnosed before it metastasizes. Utilizing SAGE analysis, a unique set of ovarian cancer biomarkers has been identified that are highly expressed in ovarian epithelial tumor

cells in comparison to normal ovarian epithelial cells. A better knowledge of the mechanisms underlying ovarian tumorigenesis will likely result in the development of novel approaches for the diagnosis and therapy of this deadly disease.

Applications: Method to diagnose ovarian cancer; Methods to treat patients with compositions that inhibit ovarian biomarkers such as siRNA.

Market: Ovarian cancer is the fourth most common form of cancer in the U.S.; Ovarian cancer is three times more lethal than breast cancer; 22,430 new cases of ovarian cancer expected in 2007; 15,280 ovarian cancer deaths in the U.S. in 2007.

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

Inventors: Patrice J. Morin *et al.* (NIA).

Related Publications:

1. KJ Hewitt, R Agarwal, PJ Morin. The claudin gene family: expression in normal and neoplastic tissues. BMC Cancer. 2006 Jul 12;6:186.

2. PJ Morin. Claudin proteins in human cancer: promising new targets for diagnosis and therapy. Cancer Res. 2005 Nov 1;65(21):9603–9606.

3. R Agarwal, T D'Souza, PJ Morin. Claudin–3 and claudin–4 expression in ovarian epithelial cells enhances invasion and is associated with increased matrix metalloproteinase–2 activity. Cancer Res. 2005 Aug 15;65(16):7378–7385.

4. CD Hough, CA Sherman-Baust, ES Pizer, PJ Morin. Use of SAGE to study gene expression in ovarian cancer. American Association for Cancer Research, 9th Annual Meeting, April 10–14, 1999, Philadelphia, Pennsylvania.

Patent Status: U.S. Provisional Application No. 60/194,336 filed 03 Apr 2000 (HHS Reference No. E–138–2000/0–US–01); PCT Patent Application No. PCT/US2001/10947 filed 03 Apr 2001, which published as WO 01/75177 on 11 Oct 2001 (HHS Reference No. E–138–2000/0–PCT–02); U.S. Patent Application No. 10/257,021 filed 03 Oct 2002 (HHS Reference No. E–138–2000/0–US–03)

Licensing Status: Available for exclusive or non-exclusive licensing.

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

Dated: June 8, 2007.

Steven M. Ferguson,

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

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Construction of Recombinant Baculoviruses Carrying the Gene Encoding the Major Capsid Protein, VP1, From Calicivirus Strains (Including Norovirus Strains Toronto, Hawaii, Desert Shield, Snow Mountain, and MD145–12)

Description of Technology: The noroviruses (known as ''Norwalk-like viruses'') are associated with an estimated 23,000,000 cases of acute gastroenteritis in the United States each year. Norovirus illness often occurs in outbreaks, affecting large numbers of individuals, illustrated recently by well-publicized reports of gastroenteritis outbreaks on several recreational cruise ships and in settings such as hospitals and schools. Norovirus disease is clearly important in terms of medical costs and missed workdays, and accumulating data support its emerging recognition as important agents of diarrhea-related morbidity.

Because the noroviruses cannot be propagated by any means in the laboratory, an important strategy in their study is the development of molecular biology-based tools. This invention reports the development of recombinant baculoviruses carrying the capsid gene from several caliciviruses associated with human disease. Growth of these baculovirus recombinants in insect cells results in the expression of virus-like particles (VLPs) that are antigenically indistinguishable from the native calicivirus particle. These VLPs can be purified in large quantities for use as diagnostic reagents and potential vaccine candidates.

Inventors: Kim Y. Green, Judy F. Lew, Adriene D. King, Stanislav V. Sosnovtsev, Gael M. Belliot (NIAID).

Publication: An example of the application of these materials is further described in KY Green *et al.*, ''A predominant role for Norwalk-like viruses as agents of epidemic gastroenteritis in Maryland nursing homes for the elderly,'' J. Infect. Dis. 2002 Jan. 15;185(2):133–146.

Patent Status: HHS Reference No. E–198–2003/0—Research Material.

Licensing Status: The materials embodied in this invention are available nonexclusively through a biological materials license.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*

Collaborative Research Opportunity: The Laboratory of Infectious Diseases, NIAID, NIH, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize norovirus VLP antigens. Please contact Kim Y. Green at *kgreen@niaid.nih.gov* for more information.

Full-Length cDNA Clone Representing the Consensus Sequence of the RNA Genome of a Human Norovirus (strain MD145–12) That Encodes Biologically Active Proteins

Description of Technology: The invention provides for a full-length cloned cDNA copy of the RNA genome of a predominant norovirus strain (Genogroup II.4) designated MD145–12 that was associated with human gastrointestinal illness. The noroviruses, which were formerly known as ''Norwalk-like'' viruses are estimated to cause 23 million cases of acute gastroenteritis in the USA each year. The virus has been designated into category B of the CDC biodefense-related priority pathogens because it can be used as an agent of bioterrorism. The subject cDNA clone of the virus encodes proteins of the MD145–12 strain that, when expressed in vitro, exhibit properties that would be expected from those produced by the original infectious virus. This cDNA clone is presently the only source to obtain norovirus proteins to facilitate studies