avenue for open dialogue between the biologics industry and CBER.

B. Site Selection

CBER will be responsible for all travel expenses associated with the site visits. Therefore, selection of potential facilities will be based on the coordination of CBER's priorities for staff training as well as the limited available resources for this program. In addition to logistical and other resource factors to consider, a key element of site selection is a successful compliance record with FDA or another Agency with which we have a memorandum of understanding. If a site visit also involves a visit to a separate physical location of another firm under contract to the applicant, the other firm also needs to agree to participate in the program, as well as have a satisfactory compliance history.

III. Requests for Participation

Identify requests for participation with the docket number found in the brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (*see* **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 24, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1753 Filed 1–26–11; 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.

Allele Specific shRNA for Nanog, and Its Use To Treat Cancer

Description of Technology: Cancer stem cells are currently thought to be major participants in resistance to radiation therapy and chemotherapy; they are also thought to drive the spread of cancer through metastasis. It has been postulated that genes involved in early embryogenesis, primarily transcription factor Nanog but also Oct4 and SOX2, may be reactivated to maintain the properties of cancer stem cells, any treatment that inhibits such genes may therefore inhibit the progression of cancer and lead to improved survival and other clinical outcomes.

The NIH investigators discovered that the expression of NanogP8, a pseudogene of Nanog, is upregulated in human colorectal cancer spheroids formed in serum-free medium. NanogP8 has also been reported to be upregulated in human prostate cancer and glioblastomas. An inhibitory RNA molecule was identified by the investigators to knock down expression of NanogP8, without interfering with expression of Nanog. The discovery may improve the safety of a shRNA-based gene therapy and improve its chances for acceptance as a clinical therapy.

Applications and Market:

• This invention may provide a new therapy to target colorectal cancer as well as a few other cancers for treatment.

• Cancer is the second leading cause of death, and colorectal cancer is the fourth most common form of cancer in the U.S. Development of more effective cancer therapies is always in need.

Development Status: Pre-clinical stage of development.

Inventors: John M. Jessup and Jingyu Zhang (NCI).

Patent Status: U.S. Provisional Application No. 61/420,214 filed 06 Dec 2010 (HHS Reference No. E–294–2010/0–US–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Experimental Carcinogenesis is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this specific gene therapy to target colorectal and other human carcinomas. Please contact John Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Compositions and Methods for Controlling Neurotropic Viral Pathogenesis by Micro-RNA Targeting

Description of Technology: There are more than seventy (70) single-stranded, positive-sense RNA viruses in the arthropod-borne flavivirus genus of the Flaviviridae family, many of which are important human pathogens that cause a devastating and often fatal neuroinfection. Flaviviruses are transmitted in nature to various mammals and birds through the bite of an infected mosquito or tick; they are endemic in many regions of the world and include mosquito-borne yellow fever (YFV), Japanese encephalitis (JEV), West Nile (WNV), St. Louis encephalitis (SLEV), dengue viruses (DEN) and the tick-borne encephalitis viruses (TBEV). During the past two decades, both mosquito-borne and tick-borne flaviviruses have emerged in new geographic areas of the world where previously they were not endemic and have caused outbreaks of diseases in humans and domestic animals.

Long-term experience with the only two successful live attenuated flavivirus vaccines has demonstrated that live attenuated virus vaccines are an efficient approach to prevent diseases caused by virulent flaviviruses because, in most cases, just a single dose of the vaccine provides a long-lasting protective immunity in humans that mimics the immune response following natural infection.

This application claims recombinant attenuated neurotropic flaviviruses comprising nucleic acid sequences complementary to the target sequences of microRNAs. The application also claims live attenuated chimeric flaviviruses, where the first flavivirus is a different flavivirus from the second flavivirus.

Applications:

• Vaccines for the prevention of multiple flavivirus infections.

• Use of human clinically-tested live attenuated dengue vector.

Advantages:

• Novel vaccine candidate.

• Rapid production time.

• Low manufacturing cost.

Development Status: Preclinical studies have been conducted by the inventors.

Inventors: Alexander Pletnev and Brian Heiss (NIAID).

Patent Status: U.S. Provisional Application No. 61/455,261 filed 14 Oct 2010 (HHS Reference No. E–197–2010/0–US–01).

Licensing Status: Available for licensing.

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

Method for Detection and Quantification of PLK1 Expression and Activity

Description of Technology: Polo-like kinase 1 (Plk1) plays a role in the regulation of the cell cycle and control of cellular proliferation. Because Plk1 is associated with neoplastic transformation of human cells, expression of this protein has been proposed as a prognostic marker for many types of malignancies. In mammalian cells, four Plks exist, but their expression patterns and functions appear to be distinct from each other. Available for licensing is a Plk1 ELISA assay using peptide substrates that are specific for Plk1, in that they are phosphorylated and bound by Plk1, but not by the related polo kinases Plk2, Plk3 and Plk4.

By exploiting a unique Plk1-dependent phosphorylation and binding property, an easy and reliable ELISA assay has been developed to quantify Plk1 expression levels and kinase activity. With this highly sensitive assay, Plk1 activity can be measured with 2–20 microgram of total lysates without immunoprecipitation or purification steps. Since deregulated Plk1 expression has been suggested as a prognostic marker for a wide range of human malignancies, this assay may provide an innovative tool for assessing the predisposition for cancer development, monitoring cancer progression, and estimating the prognosis of various types of cancer patients.

Applications:

• Optimized PBIP1 polypeptides, a natural substrate of Plk1, with enhanced specificity and sensitivity over the native PBIP1 sequence.

• ELISA assay to quantify Plk1 expression and kinase activity.

Advantages:

• Rapid, highly sensitive assay that requires lower amounts of starting material than conventional immunoprecipitation assays.

• Assay that is selective for Plk1.

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

Market:

• Cancer is the second leading cause of death in United States.

• An estimated 1,529,560 new cancer cases and 569,490 deaths from cancer occurred in the United States in 2010.

• *In vitro* cancer diagnostic market will be worth an estimated $8 billion by the end of 2012.

Inventors: Kyung S. Lee and Jung-Eun Park (NCI).

Publications:

1. JE Park *et al.* Direct quantification of polo-like kinase 1 activity in cells and tissues using a highly sensitive and specific ELISA assay. Proc Natl Acad Sci USA. 2009 Feb 10;106(6):1725–1730. [PubMed: 19181852]

2. KS Lee *et al.* Mechanisms of mammalian polo-like kinase 1 (Plk1) localization: self-versus non-self-priming. Cell Cycle 2008 Jan;7(2):141–145. [PubMed: 18216497]

3. KS Lee *et al.* Self-regulated mechanism of Plk1 localization to kinetochores: lessons from the Plk1–PBIP1 interaction. Cell Div. 2008 Jan 23;3:4. [PubMed: 18215321]

4. YH Kang *et al.* Self-regulated Plk1 recruitment to kinetochores by the Plk1–PBIP1 interaction is critical for proper chromosome segregation. Mol Cell. 2006 Nov 3;24(3):409–422. [PubMed: 17081991]

Patent Status: U.S. Patent Application No. 12/992,887 filed 15 Nov 2010 (HHS Reference No. E–091–2008/0–US–03).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Metabolism, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the PLK1 ELISA assay described above. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Immunoglobulin-Producing Mouse Plasmacytomas

Description of Technology: Overall cancer costs in the U.S. in 2006 are estimated at $206.3 billion. The World Health Organization predicts upwards of 15 million new cancer cases globally by 2020. There remains a significant unmet need for new therapies to treat cancer, as well as a need to further understand the role of the immune system in cancer susceptibility.

Available for licensing are isolated immunoglobulin-producing mouse plasmacytomas (PCTs). Each tumor produces only one species of monoclonal immunoglobulin (Ig). When transplanted into mice, these plasma cell tumors will continue to produce only the same unique Ig molecules. Some (5–10%) of the Igs specifically bind antigens.

Applications:

• To understand the underlying process of neoplastic development.

• To identify the genes that control tumor susceptibility and resistance.

• To investigate the antigen binding activities of myeloma proteins.

• To study Ig synthesis.

• To classify the various different classes of Igs (IgG, IgA, IgM).

• As a fusion partner to make monoclonal antibodies.

Advantages: Provide an unlimited source of pure monoclonal Ig molecules.

Inventor: Michael Potter (NCI).

Relevant Publications:

1. Potter M, Fahey JL, Pilgrim HI. Abnormal serum protein and bone destruction and transmissible mouse plasma cell neoplasm (multiple myeloma). Proc Soc Exp Biol Med. 1957 Feb;94(2):327–333.

2. Nathans D, Fahey JL, Potter M. The formation of myeloma protein by a mouse plasma cell tumor. J Exp Med. 1958 Jul 1;108(1):121–130. [PubMed: 13549645]

3. Potter M, Boyce CR. Induction of plasma cell neoplasms in strain BALB/c mice with mineral oil and mineral oil adjuvants. Nature. 1962 Mar 17;193:1086–1087.

4. Andersen PN, Potter M. Induction of plasma cell tumors in BALB/c mice with 2,6,10,14-tetramethylpentadecane (pristane). Nature. 1969 Jun 7;222(5197):994–995.

Patent Status: HHS Reference No. E–277–2001/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Status: Available for biological materials licensing only.

Licensing Contact: Patrick P. McCue, Ph.D.; 301–435–5560; *mccuepat@mail.nih.gov.*

Dated: January 19, 2011.

Richard U. Rodriguez,

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

[FR Doc. 2011–1669 Filed 1–26–11; 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.