Licensing Contact: Kevin W. Chang, PhD; 301–435–5018; *changke@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research, Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of hydrophobic crosslinkers for their use in vaccine development. Interested collaborators are also invited to provide statements for proposed *in vitro* or *in vivo* studies using various enveloped viruses. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Indoline Compounds for the Treatment of Spinal Muscular Atrophy (SMA) and Other Diseases

Description of Technology: With the goal to treat SMA in patients, several indoline compounds were made and tested for activity. Tests in cells demonstrate that these drugs increased the levels of active SMN protein. This is encouraging since low levels of this protein appears to be the cause of neuronal death that leads to SMA. This class of compounds appears to operate via read-through of a non-sense stop-codon to produce full length, functional protein in SMA models. This mechanism may have utility in several other neurological disorders, including cystic fibroses and Duchene's Muscular Dystrophy.

In addition, these compounds have also been shown to increase the concentration of a glutamate transporter protein in cells, which acts to recover glutamate back into neurons after release. Since the toxic effect of unrecovered excess glutamate is observed in many notorious neurological conditions, these compounds have potential for prevention or treatment.

Applications:

• Treatment of SMA in infants and children.

• Treat genetic-based diseases that result from a premature stop of protein synthesis such as muscular dystrophy and cystic fibrosis.

• Treating or preventing neurological diseases presenting glutamate toxicity like multiple sclerosis, Parkinson's, Alzheimer's, amyotrophic lateral sclerosis (ALS), or others.

Market:

• SMA is a rare genetic disease estimated to affect 1 in 6,000 births and leading genetic cause of death in infants and toddlers.

• Over 25,000 Americans are believed to suffer from SMA and the market size has been estimated between $250 million and $750 million.

Development Status: Pre-clinical, Toxicology and Safety Studies, Animal Models (Dogs and Primates).

Inventors: Jill E. Heemskerk (NINDS) *et al.*

Related Publication: MR Lunn, DE Root, AM Martino, SP Flaherty, BP Kelley, DD Coovert, AH Burghes, NT Man, GE Morris, J Zhou, EJ Androphy, CJ Sumner, BR Stockwell. Indoprofen upregulates the survival motor neuron protein through a cyclooxygenase-independent mechanism. *Chem Biol.* 2004 Nov;11(11):1489–1493.

Patent Status:

• U.S. Provisional Application No. 60/975,675 filed 27 Sept 2007 (HHS Reference No. E–187–2007/0–US–01);

• PCT Application No. PCT/US2008/077936 filed 26 Sep 2008 (HHS Reference No. E–187–2007/0–PCT–02).

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

Licensing Contact: Norbert Pontzer, PhD, JD; 301–435–5502; *pontzern@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Neurological Disorders and Stroke is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize drugs for the treatment of SMA, as well as investigation into novel uses for these indoline compounds. Please contact Dr. Melissa Maderia at *maderiam@mail.nih.gov* or 301–451–3943 for more information.

Discovery of and Use of Fragments of DOC1 as Antiangiogenic and Antitumor Therapy

Description of Technology: This invention describes small cDNA fragments of the coding region for wild type filamin A interacting protein 1-like (FILIP1L), previously known as *down-regulated in ovarian cancer 1-like* (DOC1) and variant 2 of FILIP1L genes that encode proteins that result in the inhibition of cell migration and motility, induce cell apoptosis and inhibit cell proliferation. These effects can be seen on endothelial cells and on tumor cells. These coding sequences have successfully been delivered to endothelial cells and tumor cells both in vitro and in vivo, and have demonstrated significant anti-tumor activity. In addition, the inventors have for the first time expressed the recombinant protein and developed antibodies to detect the protein fragments by Western, ELISA and immunohistochemistry. The significance of this invention is that it could provide for a series of new anti-cancer therapeutics and for the diagnostic means to follow their expression levels.

Applications: This invention could provide new anti-cancer therapeutics and diagnostics.

Market:

• An estimated 1,444,920 new cancer diagnoses in the U.S. in 2007.

• 600,000 deaths caused by cancer in the U.S. in 2006.

• Cancer is the second leading cause of death in the U.S.

• Cancer drug market will likely double to $50 billion in 2010 from $25 billion in 2006.

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

Inventors: Steven K. Libutti et al. (NCI).

Relevant Publication: Mijung Kwon et al. Functional characterization of filamin A interacting protein 1-like, a novel candidate for antivascular cancer therapy. *Cancer Res.* 2008 Sep 15;68(18):7332–7341.

Patent Status: U.S. Provisional Application No. 61/005,363 filed 03 Dec 2007 (HHS Reference No. E–166–2007/0-US–01).

Licensing Status: Available for exclusive and non-exclusive license.

Licensing Contact: Adaku Nwachukwu, JD; 301–435–5560; *madua@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute Hatfield Clinical Research Center is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Discovery of and Use of Fragments of DOC1 as Antiangiogenic and Antitumor Therapy. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 3, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–26786 Filed 11–10–08; 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.

Therapeutic Targeting of CSN5, a Negative Regulator of p53 and p27, in Human Hepatocellular Carcinoma

Description of Technology: Hepatocellular carcinoma (HCC) represents an extremely poor prognostic cancer that remains one of the most common and aggressive malignancies worldwide. Elevated expression of COP9 complex homolog subunit 5 (CSN5) in early HCC indicates that CSN5 is one of the early markers of malignant conversion. COP9 complex homolog subunit 5 (CSN5) is a multifunctional protein that interacts with a variety of proteins and targets p53 for cell degradation.

Available for licensing are CSN5 siRNAs and nucleic acid-lipid siRNA particles as cancer therapies. HCC cells treated with CSN5 siRNAs inhibited HCC progression and increased apoptosis *in vitro* and *in vivo* suggesting that CSN5 is an effective target for the development of cancer treatments.

Applications:

- siRNA cancer therapeutics.
- Nucleic acid-lipid siRNA particles for targeted drug delivery.
- Method to treat cancer.

Development Status: Early stage of development.

Market:

- HCC is the most frequent primary malignant tumor of the liver with a world incidence of 1 million new cases per year.
- The global cancer therapeutic market is expected to grow from $23.1 billion in 2004 to $60.6 billion in 2011. The targeted therapy segment is providing the growth of the entire market with an expected compound annual growth rate of 24.1 percent for 2004–2011.

Inventors: Snorri Thorgeirsson (NCI), Yun-Han Lee (NCI), *et al.*

Patent Status: U.S. Provisional Application No. 61/045,251 filed 15 Apr 2008 (HHS Reference No. E–174–2008/0–US–01).

Publication: JS Lee *et al.* Classification and prediction of survival in hepatocellular carcinoma by gene expression profiling. *Hepatology* 2004 Sept;40(3):667–676.

Licensing Status: Available for non-exclusive licensing.

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

Computer Aided Scoring and Analysis (CASA) for Rapid and Robust Detection of Biological Molecules in Tissue Microarrays

Description of Technology: Tissue Microarray (TMA) technology is a technique that allows tissue samples to be miniaturized and biologically characterized. The results can be stored digitally and analyzed manually for the expression of biological molecules which can permit the diagnosis or prognosis of disease. Despite its practical use, the current method of manually analyzing TMA samples is subjective and lacks the standardization and concordance needed to support consistent interpretation of the results. This leads to a low correlation in the results obtained amongst different laboratories and detection agents.

The current invention, Computer Aided Scoring and Analysis (CASA), provides a means of rapidly and consistently analyzing the expression patterns of biological molecules in large quantities of tissue samples. This software uses novel algorithms which normalize the pixel data obtained from digital images of the samples, statistically determines which biological molecules are diagnostic markers for the disease, and compares these data to normal, as well as diseased or abnormal tissue samples, to diagnose or predict susceptibility to the disease. In some applications, two or more biological molecules can be simultaneously screened or identified using two or more detection agents making the CASA system amenable to methods such as cluster analysis. This type of analysis can not only identify groups of antigens that are associated with a disease, but can also combine this information with characteristics of the patient population, such as age, gender or ethnicity to achieve a predictive output. The CASA system can analyze data from a broad range of detection agents such as antibodies, radionuclides, dyes and quantum dots making it a very attractive tool for high throughput TMA analysis.

The system has already been used successfully for the diagnosis and prognosis of non-small cell lung cancer in tissue samples and can be adapted for use in many diseases where changes in the expression of one or more biological molecules will to be detected.

Applications:

- Large scale diagnosis of tissue expression patterns of biological molecules.
- Rapid, robust tissue diagnosis or prognosis of disease.
- Compatible with wide range of detection agents.

Development Status: Early Stage.

Inventors: Abbas Shakoori and Jin Jen (NCI).

Patent Status: U.S. Provisional Application No. 61/034,868 filed 07 Mar 2008 (HHS Reference No. E–126–2008/0–US–01).

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

Licensing Contact: Jeffrey A. James, PhD; 301–435–5474; *jeffreyja@mail.nih.gov*.

Predictive Test for Age-Related Macular Degeneration in Asymptomatic Individuals

Description of Technology: Age-related macular degeneration (ARMD) is the leading cause of severe, irreversible vision loss for those over the age of fifty in the United States and in other developed countries. Thirteen million Americans over the age of forty have ARMD. ARMD is caused by the deterioration of the central area of the retina, or macula, resulting in a loss of central vision. This disease is believed to be a multigenic disorder, and is triggered by environmental factors such as smoking, age or diet in genetically susceptible individuals.

The present invention describes a highly predictive genetic test for universal practical clinical use to identify individuals at increased risk for ARMD. It comprises a rapid, accurate and affordable genetic screen, utilizing DNA microarray technology on a single chip. Sixteen genes are screened for 90 mutations/polymorphisms associated with ARMD, with a high predictive power (up to 92.7%) to identify asymptomatic carriers at risk. Accurate prediction of genetic susceptibility to this disorder will allow interventions to protect at-risk individuals.

Applications:

- Method to diagnose ARMD.
- Diagnostic kit to identify asymptomatic individuals at risk for ARMD.
- Method to identify genetic factors in an affected individual, aiding in the

development of a tailored therapeutic plan.

• Provide genetic epidemiologic data to elucidate the role of genetic factors in the progression of the disease.

Advantage: Easy, rapid high-throughput method to diagnose ARMD.

Development Status: This technology requires analytic validation before commercialization.

Market: There are an estimated 15 million cases of age-related macular degeneration in the United States, and 50 million cases worldwide.

Inventors: Cigdem F. Dogulu, Owen M. Rennert, Wai-Yee Chan (NICHD)

Patent Status:

• U.S. Patent Application No. 12/089,694 filed 09 Apr 2008 (HHS Reference No. E–023–2006/0–US–07).

• Australian Patent Application No. 2006311966 filed 02 Nov 2006 (HHS Reference No. E–023–2006/0–AU–03).

• Canadian Patent Application No. 2,627,686 filed 02 Nov 2006 (HHS Reference No. E–023–2006/0–CA–04).

• European Patent Application No. 06836855.4 filed 02 Nov 2006 (HHS Reference No. E–023–2006/0–CA–04).

• Japanese Patent Application No. 2008–539046 filed 01 May 2008 (HHS Reference No. E–023–2006/0–JP–06).

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

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

Collaborative Research Opportunity: The NICHD Section on Clinical Genomics is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Method Evolved for Recognition and Testing of Age-Related Macular Degeneration (MERT–ARMD). Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 3, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–26787 Filed 11–10–08; 8:45 am]

BILLING CODE 4140–01–P

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National Institutes of Health

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Radiation Induced and Targeted Chemotherapy

Description of Technology: The invention relates to a novel method of targeted chemotherapy for the treatment of cancer using hydrophobic photoactivatable compounds like 1,5-iodoanpthylazide (INA) and its analogues. The invention evolved from the discovery that electron dense atom-containing photoactivatable compounds can be activated by radiation (i.e., by x-rays and/or ultrasound) to form reactive intermediates that are highly toxic to living cells. Such compounds are termed ''radiation-activatable'' compounds. These radiation-activatable compounds do not become toxic until activated by radiation which allows for the targeting of the toxic compound by irradiation. Preliminary in vitro data show that INA and its derivatives can quickly and efficiently kill tumor cell lines upon irradiation.

Applications: Cancer Treatment.

Advantages: Novel method of cancer treatment.

Development Status: In vitro data can be provided upon request.

Market: Cancer Therapy.

Inventors: Yossef Raviv *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 61/026,654 filed 06 Feb 2008 (HHS Ref. No. E–256–2007/0-US–01).

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

Licensing Contact: Kevin W. Chang, PhD, 301–435–5018, *changke@mail.nih.gov.*

Small-Molecule Modulators of the Thyroid-Stimulating Hormone (TSH) Receptor

Description of Technology: The thyroid gland plays a major role in the body, secreting hormones that regulate the metabolic rate, production of other hormones, and the growth and maturation of body tissues. Thyroid disorders affect energy metabolism, neurological state, fertility, cardiovascular condition, and other body functions. In patients with hyperthyroidism, or an overactive thyroid gland, the disease is often caused by autoimmune over-stimulation of the thyroid gland (Graves' disease), or by thyroid tumors. Drugs currently used for short-term treatment of hyperthyroidism inhibit synthesis of thyroid hormones, although long-term treatment usually requires removal of the thyroid gland by surgery or administration of radioiodine. Hypothyroidism, or an underactive thyroid gland, can be caused by autoimmune disease, atrophy of the thyroid gland, or through a deficiency of thyroid-stimulating hormone (TSH). TSH, produced by the pituitary gland, binds to the TSH receptor in the thyroid to stimulate thyroid hormone production. Hypothyroidism is typically treated by direct replacement of the thyroid hormones.

The inventors have discovered a series of low-molecular weight compounds that act as TSH receptor antagonists (inhibitors) or agonists (activators). Antagonists of the TSH receptor could be used to treat hyperthyroidism, with the advantage of directly downregulating the TSH receptor, rather than inhibiting thyroid hormone synthesis. Agonists of the TSH receptor could be used to monitor thyroid activity and potential cancer recurrence in patients who have been treated for thyroid cancer, and may also be useful for treatment of certain forms of hypothyroidism. Additionally, some compounds in this family may be useful for treatment of fertility and reproductive disorders involving the luteinizing hormone/choriogonadotropin (LH/CG) receptor and the follicle-stimulating hormone (FSH) receptor, which are structurally related to the TSH receptor.

Applications:

• Development of therapeutics for hyperthyroidism or hypothyroidism.

• Development of diagnostic tools for evaluation of thyroid cancer patients.

• Development of therapeutics for infertility.

Market: Approximately 1 in 13 Americans suffers from a thyroid