[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, 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. 209 and 37 CFR part 404 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.

FOR FURTHER INFORMATION: 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.

Device for Vascular Dilation

Description of Technology: The invention is an enhanced vascular dilator that eliminates the vascular injury caused by the size mismatch between vascular introducer sheaths and vascular dilators, as the two are advanced into a blood vessel. The invention provides a "shoulder" to match the diameter of the introducer sheath so that there is a smooth transition, without size mismatch, between the dilator and the introducer sheath. The invention allows the dilator to be withdrawn in segments from the introducer sheath. This is especially valuable to reduce vascular injury when using large-bore introducer sheaths for interventional procedures including transcatheter valves and endografts.

Potential Commercial Applications:

• Caval access

• Vascular access

Competitive Advantages: Non-perforating

Development Stage: Prototype

Inventors: Robert Lederman (NHLBI), Ozgur Kocaturk (NHLBI), Adam Greenbaum (Henry Ford Hospital)

Intellectual Property: HHS Reference No. E-759-2013/0 – US Provisional Patent Application 61/890,961 filed 15 October 2013

Licensing Contact: Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov

Collaborative Research Opportunity: The National Heart, Lung, and Blood Institute is seeking statements of capability or interest from parties interested in

collaborative research to further develop, evaluate or commercialize interventional catheter-based procedures to reduce vascular injury. For collaboration opportunities, please contact Peg Koelble at koelblep@nhlbi.nih.gov.

Her2 Monoclonal Antibodies, Antibody Drug Conjugates, and Site Specific Antibody Conjugate Methods

Description of Technology: Antibody drug conjugates (ADC) can demonstrate high efficacy as cancer therapeutics, however, much more can be done to improve their efficacy and safety profile. Site-specific antibody drug conjugation is a promising way to do this.

The scientists at the NIH have identified a fully human monoclonal antibody, m860, that binds to cell surface-associated Her2 with affinity comparable to that of Trastuzumab (Herceptin) but to a different epitope. In addition, the scientist developed a site-specific glycan engineering method to conjugate the antibody to the small molecule drug auristatin F. The ADC prepared though this site-specific approach shows very good stability, cell surface binding activity and also potent specific cell killing activity against Her2 positive cancer cells, including Trastuzumab resistant breast cancer cells. This ADC has the potential to be developed as a targeted therapeutic for Her2-overexpressing cancers and this site-specific strategy could be readily applied to develop ADCs targeting other cancers that express cell surface markers or other disease targets.

Potential Commercial Applications:

• Therapeutic for the treatment of Her2 positive cancers.

• Method for producing safer and more effective ADCs.

Competitive Advantages:

• Could be used in combination with Trastuzumab or for patients who have developed resistance to Trastuzumab treatment, since this antibody targets a different epitope.

• Site specific conjugation provides better efficacy and less side effects than ADCs produced using traditional strategies.

• Can be readily applied to develop ADCs targeting other cancers that express cell surface markers or other disease targets, such as HIV.

Development Stage:

• Pre-clinical

• In vitro data available

• In vivo data available (animal)

Inventors: Dimiter S. Dimitrov (NCI), Zhu Zhongyu (NCI), Pradman K. Qasba (NCI), Boopathy Ramakrishnan (NCI)

Intellectual Property: HHS Reference No. E-351-2013/0 – US Provisional Application No. 61/833,732 filed 11 June 2013

Licensing Contact: Whitney A. Hastings; 301-451-7337; hastingw@mail.nih.gov

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize monoclonal antibodies, ADCs, and methods. For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

Non-invasive Early Stage Lung Cancer Diagnostic and Prognostic Assays

Description of Technology: The present invention provides a unique non-invasive diagnostic to detect early stage lung cancer and predict patient survival through a simple assay utilizing urine samples. Urine samples minimize patient discomfort unlike current early detection methods that are highly invasive, such as a biopsy or bronchoscopy, or utilize expensive computer tomography (CT) scans that expose patients to harmful radiation. Although the sensitivity of low dose CT scans is high, the specificity is low, resulting in high false positive rates. Utilizing metabolic profiling of urine samples obtained from 1,005 people, the scientists have developed and validated this unique metabolite profile that diagnoses early stage lung cancer and predicts patient survival with a high accuracy.

Potential Commercial Applications:

• Diagnostic test for early stage lung cancer

• Prognostic test for patient survival

• Method to help physicians make informed treatment decisions

Competitive Advantages: Urinary patient samples - no need for needles, invasive surgery, or claustrophobic tests

Development Stage:

• Early-stage

• In vivo data available (human)

Inventors: Curtis Harris (NCI), Majda Haznadar (NCI), Frank Gonzalez (NCI), Ewy Mathe (NCI), Kristopher Krausz (NCI), Soumen Manna (NCI), and Andrew Patterson (Pennsylvania State University)

Intellectual Property: HHS Reference No. E-121-2013/0 – US Patent Application No. 61/845,055 filed 11 July 2013

Related Technology: HHS Reference No. E-248-2002/0 – US Patent Application No. 10/533,459 filed 02 May 2005; PCT Application No. PCT/US2013/055746 filed 20 August 2013

Licensing Contact: Jennifer Wong, M.S.; 301-435-4633; wongje@mail.nih.gov

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Human Carcinogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Non-invasive Urinary Biomarkers Highly Predictive of Non-small Cell Lung Cancer Status and Survival. For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

Intravenous Water Soluble Formulation of MJC13 – A Novel Lead Compound for the Treatment of Castrate-resistant Prostate Cancer

Description of Technology: Normal prostate growth and maintenance is dependent on androgens acting through the androgen receptor (AR). AR expression is maintained and plays an important role throughout prostate cancer progression. A lead molecule, MJC13, has been identified and has higher potency and better selectivity for AR than any other compound tested. It has been shown to effectively block AR-

dependent gene expression in cellular models of prostate cancer at micromolar concentrations.

MJC13, although an attractive drug candidate, has low aqueous solubility. This has hindered the clinical development of MJC13. Scientists at NIH, University of Texas-El-Paso and Texas Southern University have developed a water soluble and stable MJC13 liquid dosage formulation that is suitable for intravenous administration. The solubility of this formulation has increased over 25,000 times compared to MJC13 itself. Additionally, a sensitive LC/MS/MS method to analyze MJC13 has also been developed, which can detect as little as 1 ng/mL of MJC13 in solution or plasma. These studies are of great importance for future pre-clinical and clinical studies of MJC13.

Potential Commercial Applications: Develop MJC13 as a clinical drug product for the treatment of castrate-resistant prostate cancer (CRPC), in which current treatment options are ineffective.

Competitive Advantages: Water soluble formulation of the lead compound, MJC13, that will enable further pharmacokinetic/ pharmacodynamic studies and clinical studies required for commercial development of the drug.

Development Stage:

• Pre-clinical

• In vitro data available

• In vivo data available (animal)

Intellectual Property: HHS Reference No. E-065-2013/0 – US Provisional Application No. 61/788,716 filed 15 March 2013

Related Technology: HHS Reference No. E-162-2009/0 – US Patent Application No. 13/395,976 filed 14 March 2012

Licensing Contact: Eggerton Campbell, Ph.D.; 301-435-5282; campbellea2@mail.nih.gov

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology with an initial goal of preclinical evaluation and an ultimate goal of clinical testing. For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

Methods of Modulating Chemotherapeutic Cytotoxicity

Description of Technology: Investigators at the National Cancer Institute (NCI) have discovered that blockade of the signalling activity of a single cell-surface receptor, CD47, in cancer cells results in enhanced sensitivity of cancer cells to chemotherapy treatment and in healthy tissues reduces damage to normal cells. Many chemotherapeutic agents cause significant cytotoxicity to non-cancer ("normal") cells, resulting in undesirable side-effects and often limiting the dose and/or duration of chemotherapy that can be administered to a patient. The present invention relates to a method of using CD47-modulating compounds in combination with a chemotherapeutic agent to increase the efficacy of that agent against inhibiting tumor growth. The invention also relates to methods for preventing damage to heart tissue associated with the use of anthracycline chemotherapy. The current invention builds on the NIH's previous discoveries of

antibodies, antisense morpholino oligonucleotides, and peptide compounds that modulate CD47.

Potential Commercial Applications: Combination Chemotherapy

Competitive Advantages:

• Enhance effectiveness of chemotherapeutic agents

• Limit off target effects on normal tissue

• Reduces cytotoxicity of normal cells

• Provides cardioprotection for anthracyclines

Development Stage:

• Early-stage

• Pre-clinical

• In vitro data available

• In vivo data available (animal)

Inventors: David D. Roberts and David R. Soto Pantoja (NCI)

Publication: Soto-Pantoja DR, et al. CD47 deficiency confers cell and tissue radioprotection by activation of autophagy. Autophagy. 2012 Nov;8(11):1628-42. [PMID 22874555]

Intellectual Property: HHS Reference No. E-296-2011/0 – US Application No. 61/779,587 filed 13 March 2013

Related Technology: HHS Reference No. E-227-2006/5 –

• US Application No. 12/444,364 filed 03 April 2009

• CA Application No. 2,665,287 filed 05 October 2007

• EP Application No. 07868382.8 filed 27 March 2009

• US Application No. 13/546,941 filed 11 July 2012

• US Application No. 13/546,931 filed 11 July 2012

Licensing Contact: Charlene Maddox, Ph.D.; 301-435-4689; sydnorc@mail.nih.gov

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Pathology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize CD47 targeting therapeutics, cardioprotection, autophagy modulation. For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

Dated: November 21, 2013,

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

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