Dated: August 29, 2012.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. 2012–22593 Filed 9–12–12; 8:45 am]

BILLING CODE 4165–16–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.

FOR FURTHER INFORMATION CONTACT: 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.

Image Analysis Software for Quantitative Evaluation of Striation Patterns and Their Defects in Skeletal Muscles

Description of Technology: Available for licensing is software written in MatLab for evaluating striation patters in images of skeletal muscle fibers for better sensitivity in the quantitation of skeletal muscle disorders. Skeletal muscles have a regular, periodic organization (the periodicity of the sarcomeres), which is not only structural but also functional. Muscle pathologies create disorder in the normally periodic myofibrils. Objective grading of muscle morphology is necessary to assess muscle health, compare biopsies, and evaluate treatments and the evolution of disease.

Potential Commercial Applications: Drug development for muscular disorders.

Competitive Advantages: Automated analysis of sarcomere dysplasia for objective grading of muscle morphology.

Development Stage: Prototype.

Inventors: Wenhua Liu and Evelyn Ralston (NIAMS).

Publications:

1. Plotnikov SV, *et al.* Measurement of muscle disease by quantitative second-harmonic generation imaging. J Biomed Opt. 2008 Jul–Aug;13(4):044018. [PMID 19021346].
2. Friedrich O, *et al.* Microarchitecture is severely compromised but motor protein function is preserved in dystrophic mdx skeletal muscle. Biophys J. 2010 Feb 17;98(4):606–16. [PMID 20159157].
3. Llewellyn ME, *et al.* Minimally invasive high-speed imaging of sarcomere contractile dynamics in mice and humans. Nature 2008 Aug 7;454(7205):784–8. [PMID 18600262].

Intellectual Property: HHS Reference No. E–264–2012/0—Software Research Tool. Patent protection is not being pursued for this technology.

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

Collaborative Research Opportunity: The Light Imaging Section of NIAMS, NIH, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize software for image analysis of cells and tissues and skeletal muscle. For collaboration opportunities, please contact Wenhua Liu at *liuw5@mail.nih.gov* or 301–451–4815.

Capillary Viscometer for Measuring Viscosity of Macromolecular Solutions of Biological Relevance

Description of Technology: A capillary-based device and system for measuring the rheological properties of solutions of synthetic and biological polymers. The device automatically serially dilutes and varies the flow rate of a sample, permitting measurement of solution viscosity across wide ranges of concentration and shear rate without changing samples. The device can rapidly and accurately assay solute stability, solute-solvent and solute-solute interactions in solutions of proteins and other macromolecules of biotechnological and pharmaceutical interest, as well as solution injectability.

Potential Commercial Applications: Rapid characterization of composition-dependent rheological properties of candidate biopharmaceuticals and industrial polymers.

Competitive Advantages:

- Automatic variation of solute concentration
- Automatic variation of shear rate
- Direct measurement of solution injectability

Development Stage:

- Prototype
- *In vitro* data available

Inventors: Allen Minton and Asaf Grupi (NIDDK).

Intellectual Property: HHS Reference No. E–231–2012/0—US Provisional Application No. 61/691,209 filed 20 Aug 2012.

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

Collaborative Research Opportunity: The National Institute of Diabetes and Digestive and Kidney Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize automated capillary viscometer. For collaboration opportunities, please contact Allen P. Minton at *minton@helix.nih.gov* or Asaf Grupi at *grupia@gmail.com*.

Use of Erythropoietin and Derivatives for Treatment of Hypertension

Description of Technology: Erythropoietin (EPO), a natural hormone produced by kidneys is associated with stimulation of red blood cell production. Recombinant human erythropoietin (rhEPO) is currently used for treatment of anemia and has powerful cardioprotective properties. Hypertension remains a major health problem and a serious risk factor for stroke and chronic heart failure. Researchers at the NIH have discovered that administering a therapeutically effective dose of rhEPO or an EPO derivative including carbamylated erythropoietin (CEPO) and Helix B surface peptide (HBSP), have an acutely reducing both systolic and diastolic blood pressure, via Nitric Oxide (NO) signaling. Long-term administration of derivative of EPO, HBSP, prevents elevation of arterial blood pressure in an animal model of hypertension. Unlike long-term treatment with rhEPO, administration of EPO derivatives, such as HBSP, does not stimulate excessive red cell production and will be useful in the development of anti-hypertensive drugs.

Potential Commercial Applications: Therapeutics for treatment of hypertension.

Competitive Advantages:

- Administration of EPO and derivatives does not stimulate excessive red blood cell production
- This technology utilizes activation of natural vasodilation mechanisms

• rhEPO and EPO derivatives provide tissue-protective properties, which none of existing antihypertensive drugs does

Development Stage:

• Early-stage
• Pre-clinical
• *In vitro* data available

Inventors: Mark Talan, Ismayil Ahmet, Edward Lakatta (all of NIA).

Publication: Ahmet I, *et al.* Acute hemodynamic effects of erythropoietin do not mediate its cardioprotective properties. Biolog Open 2012, in press.

Intellectual Property:

• HHS Reference No. E–158–2012/0—U.S. Provisional Application No. 61/636,547 filed 20 Apr 2012
• HHS Reference No. E–158–2012/1—U.S. Provisional Application No. 61/638,328 filed 25 Apr 2012
• HHS Reference No. E–158–2012/2—U.S. Provisional Application No. 61/656,698 filed 07 Jun 2012

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *Fatima.Sayyid@nih.hhs.gov*.

Collaborative Research Opportunity: The National Institute on Aging is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize new anti-hypertensive drug based of non-erythropoietic derivatives of erythropoietin that combines vasodilative and tissue protective properties. For collaboration opportunities, please contact Vio Conley, M.S. at *conleyv@mail.nih.gov*.

High-Affinity Mouse Monoclonal Antibodies to Glypican-3 (GPC3) for Treatment of Cancer

Description of Technology: Liver cancer is the fifth most common cancer in the world, with hepatocellular cancer (HCC) representing the preponderance of these liver cancers. As with many cancers, positive prognosis for a patient diagnosed with HCC correlates with the early detection of the disease. Unfortunately, HCC is usually detected at a late stage in its development, leading to poor prognosis for most patients. As a result, there is great interest and value in developing new agents which can detect the presence of HCC in a patient at an early stage.

Glypican-3 (GPC3) is a cell surface heparan sulfate glycoprotein that is expressed on the vast majority of HCC cells. The correlation between GPC3 expression and HCC makes GPC3 an attractive candidate for studying the disease progression and treatment of HCC. The presence, progression and treatment of this disease can potentially be monitored by tracking the level of expression of GPC3 on cells. This can be accomplished using monoclonal antibodies which recognize only GPC3, particularly the cell surface domain of the protein. This invention concerns the generation of several monoclonal antibodies that are specific for the cell surface domain of GPC3 (YP6, YP7, YP8, YP9 and YP9.1), and which can be used either as therapeutic candidates for treating GPC3-related diseases or as research reagents for studying the role of GPC3 in HCC.

Potential Commercial Applications: Monoclonal antibodies for use as therapeutics, including:

• Treatment of HCC as a stand-alone antibody
• Treatment of HCC as an antibody-drug conjugate, such as an immunotoxin

Antibodies for use as research materials, including:

• Detection of cells that express GPC3 for monitoring HCC disease progression and treatment
• Immunostaining for tumor imaging
• ELISA and immunohistochemistry applications
• Any other antibody-related research use, including immunoprecipitation, western blot analysis, etc.

Competitive Advantages:

• Higher binding affinity (subnanomolar levels) than commercially available GPC3 antibodies such as 1G12
• Increased binding activity potentially improves therapeutic value through improved specificity and lower effective drug concentrations
• Recognition of cells with low levels of GPC3 expression
• Able to bind to wild-type GPC3 (conjugated to heparan sulfate) better than the GPC3 core protein (lacking heparan sulfate)

Development Stage:

• Early-stage
• *In vitro* data available
• *In vivo* data available (animal)

Inventors: Mitchell Ho *et al.* (NCI).

Publications:

1. Ho M, Kim H. Glypican-3: A new target for cancer immunotherapy. Eur J Cancer. 2011 Feb;47(3):333–8. [PMID 21112773].
2. Ho M. Advances in liver cancer antibody therapies: A focus on glypican-3 and mesothelin. BioDrugs. 2011 Oct 1;25(5):275–84. [PMID 21942912].
3. Phung Y, *et al.* High-affinity monoclonal antibodies to cell surface tumor antigen glypican-3 generated through a combination of peptide immunization and flow cytometry screening. MAbs. 2012 Sep 1;4(5):592–9. [PMID: 22820551].

Intellectual Property: HHS Reference No. E–136–2012/0—U.S. Provisional Application No. 61/654,232 filed 01 Jun 2012.

Related Technology: HHS Reference No. E–130–2011/0—U.S. Provisional Application No. 61/477,020 filed 19 Apr 2011; PCT Application No. PCT/US2012/034186 filed 19 Apr 2012.

Licensing Contact: David A. Lambertson, Ph.D.; 301–435–4632; *lambertsond@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 is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize liver cancer therapy and diagnostics, humanization, antibody drug/toxin conjugates. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

New Targeted Therapy for Acute Myeloid Leukemia and Acute Lymphoblastic Leukemia

Description of Technology: The invention describes the use of benzodiazepine compounds for the treatment of acute myeloid leukemia (AML) and acute lymphoblastic leukemia (ALL). Specifically, the compounds can be used to treat core binding factor (CBF) leukemias, which are a subgroup of leukemia associated with the generation of fusion genes, arising from the binding between the transcription factors: Core binding factor-beta (CBF?) and runt-related transcription factor 1 (RUNX1). The compounds described in this invention have been found to inhibit the binding of CBFβ and RUNX1, resulting in selectively killing leukemia cells in culture and suppressing leukemia in a mouse model.

In addition, the binding of runt-related transcription factors from the RUNX family have been implicated in the development of other diseases, including (but not limited to): Platelet disorders, solid tumours (*e.g.,* lymphoma, breast cancer, osteosarcoma) and bone diseases (*e.g.,* osteoporosis, cleidocranial dysplasia and intervertebral disk degeneration). Thus, the use of these compounds may represent new targeted therapies for AML and ALL as well as other RUNX-related disorders.

Potential Commercial Applications:

• Targeted drug therapies for AML and ALL.
• Combination chemotherapies for AML and ALL.
• Therapies for other RUNX related disorders, including platelet disorders, solid tumours (*e.g.,* lymphoma, breast cancer, osteosarcoma) and bone diseases

(*e.g.,* osteoporosis, cleidocranial dysplasia and intervertebral disk degeneration).

Competitive Advantages:

• Proof of concept demonstrated in a mouse model.

• Compounds have been previously tested in clinical studies for anti-HIV drugs.

Development Stage:

• Early-stage.

• Pre-clinical.

• *In vitro* data available.

• *In vivo* data available (animal).

Inventors: Pu Paul Liu (NHGRI), Wei Zheng (NCATS), Juan J. Marugan (NCATS), Noel T. Southall (NCATS), Lea Cunningham (NCI).

Publication: Cunningham L, *et al.* Identification of benzodiazepine Ro5–3335 as an inhibitor of CBF leukemia through quantitative high throughput screen against RUNX1–CBFβ interaction. Proc Natl Acad Sci USA. 2012 Sep 4;109(36):14592–7. [PMID 22912405].

Intellectual Property: HHS Reference No. E–060–2011/0—

• U.S. Provisional Application No. 61/453,863 filed 17 Mar 2011

• PCT Application No. PCT/US2012/029169 filed 15 Mar 2012

Licensing Contact: Sabarni K. Chatterjee, Ph.D.; 301–435–5587; *chatterjeesa@mail.nih.gov.*

Collaborative Research Opportunity: The National Human Genome Research Institute (NHGRI), Oncogenesis and Development Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize benzodiazepine compounds described above to treat CBF leukemia, AML, ALL, and/or other RUNX-related disorders. Please contact Claire T. Driscoll, Director of NHGRI Technology Transfer Office (*cdriscoll@mail.nih.gov;* 301–594–2235) for more information.

Novel Methods for Using Biomarkers To Monitor Glucose Levels and Screen for Diabetes Risk

Description of Technology: A primary goal of diabetes therapy is to improve control of blood glucose levels (known as glycemic control) in patients. Prospective studies of both Type 1 and Type 2 diabetes indicate that careful glycemic control significantly reduces the risk of microvascular, neurological, and cardiovascular complications of diabetes. The current method of monitoring glycemic control involves measuring levels of the intracellular hemoglobin (HbA1C). However, levels of HbA1C reflect glycemic control over a timeframe of several months and are susceptible to a variety of perturbing factors such as hematologic disorders, kidney disease, aspirin or penicillin use, or alcohol intake.

This technology describes a family of novel glycated peptide and protein biomarkers for glycemic control, as well as a method to monitor glycemic control in diabetic patients. In contrast to intracellular HbA1C, this technology detects glycated plasma proteins, which may reflect changes in glycemic control more rapidly and with more sensitivity. A diagnostic test developed using this technology could be envisioned to supplement or replace current HbA1C-based glycemic monitoring and screen individuals for risk of diabetes.

Potential Commercial Applications:

• Diagnostic test to measure glycemic control in diabetic patients

• Diagnostic test to screen patients for risk of developing diabetes

Competitive Advantages:

• Detects plasma proteins rather than intracellular markers

• May provide more rapid and sensitive detection than currently used methods

Development Stage:

• Early-stage

• *In vitro* data available

Inventor: Perry J. Blackshear (NIEHS).

Intellectual Property: HHS Reference No. E–057–2005/0—

• PCT Application No. PCT/US2007/063385 filed 06 Mar 2007

• U.S. Application No. 12/281,909 filed 27 Oct 2008

Licensing Contact: Tara Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov.*

A Novel Glucocorticoid Receptor Cofactor for Use as an Adjunct to Steroid-Based Therapies

Description of Technology: Methods of using STAMP (SRC–1 and TIF–2 Associated Modulatory Protein) polypeptides for modulating steroid or nuclear receptor activity, alone or in combination with a steroid or nuclear receptor modulator. The novel protein, STAMP, modulates the trans-activation properties of glucocorticoid receptors and other steroid receptors. STAMP may be useful as a steroid-sparing agent for decreasing the severity of unwanted side-effects during steroid treatment, particularly in long-term treatment for chronic disease.

Steroid hormones such as androgens and glucocorticoids are used in the treatment of many diseases. They act to regulate many physiological responses by binding to steroid receptors. However, because steroid receptors are expressed in many tissues, efforts to therapeutically modify the effects of steroid hormones on a specific tissue or on a specific receptor of the steroid receptor family often cause undesirable effects in other tissues or on other receptors.

Potential Commercial Applications: Adjunct to steroid-based therapies for diseases such as arthritis, asthma, inflammatory and autoimmune diseases.

Competitive Advantages:

• Reduce the severity of unwanted side-effects from conventional steroid hormone therapies.

• Particularly beneficial for long-term therapies.

Development Stage:

• Early-stage

• *In vitro* data available

Inventors: S. Stoney Simons and Yuanzheng He (NIDDK).

Publications:

1. He Y, *et al.* STAMP alters the growth of transformed and ovarian cancer cells. BMC Cancer. 2010 Apr 7;10:128. [PMID 20374646]
2. He Y, Simons SS Jr. STAMP, a novel predicted factor assisting TIF2 actions in glucocorticoid receptor-mediated induction and repression. [PMID 17116691]
3. He Y, *et al.* Modulation of induction properties of glucocorticoid receptor-agonist and -antagonist complexes by coactivators involves binding to receptors but is independent of ability of coactivators to augment transactivation. [PMID 12376547]

Intellectual Property: HHS Reference No. E–056–2004/0—U.S. Patent No. 7,867,500 issued 11 Jan 2011.

Licensing Contact: Tara Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov.*

Dated: September 7, 2012.

Richard U. Rodriguez,

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

[FR Doc. 2012–22497 Filed 9–12–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial