[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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Method of Treating Fumarate Hydratase-Deficient Kidney Cancer

Description of Technology: Patients having germline fumarate hydratase ("FH") gene mutation are predisposed to develop aggressive kidney cancer with few treatment options and poor therapeutic outcomes. NCI scientists have identified a tyrosine kinase inhibitor vandetanib that is highly cytotoxic to kidney cancer cells both in vitro and in vivo. C-Abl activity is upregulated in FH-deficient kidney tumors and vandetanib efficacy is a direct consequence of c-Abl inhibition. It was also found that combining metformin enhanced the cytotoxic effect of vandetanib by inhibiting NRF2 transcriptional activity in a SIRT1-dependent manner. Thus dual inhibition of c-Abl and NRF2 activity with vandetanib and metformin is a novel therapeutic approach to target glycolytically dependent, oxidatively stressed tumors.

Potential Commercial Applications: Therapies for treating FH-deficient kidney cancer and glycolytically dependent, oxidatively stressed tumors.

Competitive Advantages:

• Specificity of mode of action may reduce potential side-effects

• Novel mode of action may increase market competition

• No effective therapy is currently available for patients with advanced FH-deficient kidney cancer.

Development Stage:

• In vitro data available

• In vivo data available (animal)

Inventors: William Marston Linehan (NCI), et al.

Publication: Sourbier C, et al. Targeting ABL1-mediated oxidative stress adaptation in fumarate hydratase-deficient cancer. Cancer Cell. 2014 Dec 8;26(6):840-50. [PMID 25490448]

Intellectual Property: HHS Reference No. E-104-2014/0 -

• US Patent Application No. 62/003,319 filed May 27, 2014

• PCT/US2015/03267 filed May 27, 2015

Licensing Contact: Whitney Hastings, Ph.D.; 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 the combination of Vandetanib and Metformin to treat fumarate hydratase-deficient cancer. For collaboration opportunities, please contact Michael Pollack, Ph.D. at pollackm@mail.nih.gov.

Therapeutic and Prophylactic Anti-Influenza Virus Neuraminidase 1 (N1) Antibody (CD6) with a Novel Epitope that Spans Neuramindase (NA) Dimers

Description of Technology: Influenza virus neuramindase (NA) protein is a surface protein that plays an essential role in virus replication. Drugs and antibodies that block NA function can reduce both the symptoms and the length of illness; however,

variants of influenza virus are resistant to NA inhibitors. The neuramindase 1 (N1) subtype of NA is important because it is found in the two pandemic H1N1 influenza virus strains (1918 Spanish flu and 2009 swine flu) and the H5N1 avian influenza virus. Anti-neuramindase antibody CD6 is a novel antibody that spans a conserved 30 amino acid epitope across the lateral face of a neuramindase (NA) dimer.

The subject technology may offer an alternative to therapeutic NA inhibitors currently available. CD6 is a potent monoclonal antibody against N1 subtypes of NA that inhibits the enzymatic activity of the NA protein, including NA variants resistant to NA inhibitors. In a murine model of infection, a single dose of antibody was protective against lethal challenge with H1N1 influenza virus. The CD6 antibody can potentially be used in combination with other antibodies in an antibody "cocktail" or in conjunction with other therapeutic agents. Additionally, this unique anti-NA antibody may be useful in combination with known neutralizing anti-hemagglutinin (HA) antibodies.

Potential Commercial Applications:

• Prophylactic and therapeutic against influenza virus infections.

• Diagnostic tests for influenza virus infections.

• Reagent to measure the potency of H1N1 NA in influenza virus vaccines.

Competitive Advantages:

• Monoclonal antibody demonstrated to be effective against circulating H1N1 influenza viruses

• Monoclonal antibody binds a novel, conserved epitope spanning NA dimers.

• Monoclonal antibody is well-suited for an antibody cocktail that includes anti-HA antibodies.

Development Stage:

• Early-stage

• In vitro data available

• In vivo data available (animal)

Inventors: Hongquan Wan (FDA), Maryna Eichelberger (FDA), Hua Yang (CDC), James Stevens (CDC), David Shore (CDC), Rebecca Garten (CDC)

Publication: Wan H, et al. Structural characterization of a protective epitope spanning A(H1N1)pdm09 influenza virus neuraminidase monomers. Nat Commun. 2015 Feb 10;6:6114. [PMID 25668439]

Intellectual Property: HHS Reference No. E-005-2015/0 - US Provisional Patent Application No. 62/088,388 filed December 5, 2014

Licensing Contact: Steven M. Ferguson; 301-435-5561; fergusos@mail.nih.gov

Collaborative Research Opportunity: The U.S. Food and Drug Administration is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Bill Ronnenberg at william.ronnenberg@fda.hhs.gov or 240-402-4561.

Confocal Laser Device and Method for Evaluating the Optical Properties of Intraocular Lenses (IOLs) including Toric IOLs

Description of Technology: This innovative technology includes a confocal laser device and methodologies to evaluate the optical properties of spherical and toric Intraocular Lenses (IOLs). Spherical and toric IOLs are implanted in the eye to treat

cataracts and other conditions in order to correct vision after surgery. Toric IOLs, in addition to correcting spherical aberrations of the eye, correct asymmetrical aberrations of the eye such as astigmatism.

This technology includes the confocal laser device and methodology for assessing spherical IOLs with an integrated component for assessing toric IOLs. The IOL market is growing steadily and IOL technology is continually improving to correct complex vision errors. It is estimated that 3 million IOLs are implanted annually in the U.S. and 19.7 million worldwide. This device can be used to precisely assess IOL key properties such as dioptric power, cylinder power, optical plane orthogonality and IOL markings used for IOL positioning in the eye during surgery. Thus, this new technology provides a simple, noninvasive, accurate and objective methodology to evaluate IOL characteristics with higher accuracy and repeatability in wider power ranges compared to the conventional test methods. These IOL test capabilities can improve the safety and efficacy of IOL implants and ultimately lead to better cataract surgery success rates.

Potential Commercial Applications:

• Development and implementation of novel test devices and independent methodologies for precise evaluation and validation of critical IOL characteristics

• Development and evaluation of novel IOL designs

Competitive Advantages:

• Higher accuracy

• Higher repeatability

• Larger range of positive and negative IOL dioptric power measurement

Development Stage:

• In vitro data available

• In situ data available (on-site)

• Prototype

Inventors: Ilko Ilev, Bennett Walker, Robert James, and Don Calogero (all of the FDA)

Publications:

1. Walker BN, et al. Assessing the effect of laser beam width on quantitative evaluation of optical properties of intraocular lens implants. J Biomed Opt. 2014 May;19(5):055004. [PMID 24817618]

2. Walker BN, et al. Impact of environmental temperature on optical power properties of intraocular lenses. Appl Opt. 2014 Jan 20;53(3):453-7. [PMID 24514132]

3. Hoffer KJ, et al. Testing the dioptric power accuracy of exact-power-labeled intraocular lenses. J Cataract Refract Surg. 2009 Nov;35(11):1995-9. [PMID 19878834]

4. Ilev IK. A simple confocal fibre-optic laser method for intraocular lens power measurement. Eye (Lond). 2007 Jun;21(6):819-23. [PMID 16710435]

Intellectual Property:

• HHS Reference No. E-047-2015/0 - US Provisional Application No. 62/108,795 filed January 28, 2015

• HHS Reference No. E-038-2005/0 - US Patent No. 8,456,738 issued June 4, 2013; EP Application 06750250.0

• HHS Reference No. E-039-2005/0 - US Patent No. 7,719,668 issued May 18, 2010; EP Application 06736741.7

Licensing Contact: Steven M. Ferguson; 301-435-5561; fergusos@mail.nih.gov

Collaborative Research Opportunity: The Food and Drug Administration is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Bill Ronnenberg at william.ronnenberg@fda.hhs.gov or 240-402-4561.

Dated: July 6, 2015.

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Richard U. Rodriguez,
Acting Director,
Office of Technology Transfer,
National Institutes of Health.

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