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 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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

A Rabbit Anti-pT1989 ATR Monoclonal Antibody for Use in Immunoassays

Description of Technology: This technology concerns a novel monoclonal antibody for selecting new anti-cancer compounds.

The active form of ATR (ataxia telangiectasia-mutated and Rad3-related) kinase is phosphorylated at Threonine 1989 site (T1989). The monoclonal antibody binds the phosphorylated Threonine 1989 (T1989). The phosphorylated ATR senses DNA damage response and leads to cell cycle arrest. Targeting at ATR, anti-cancer drugs may induce cancer cell death.

This technology can be applied into stable and immunoassays on multiple platforms for measuring ATR activation and inhibition and may inform therapeutic decisions for cancer treatment.

Potential Commercial Applications:

• Antibody specifically against phosphorylated ATR (at T1989 site).

• Application in assays to develop personalized medicine for pT1989 ATR-related disease.

• Application in assays for selecting measuring ATR modulation.

• Application in assays for selecting ATR inhibitors.

Competitive Advantages:

• Novel antibody against ATR phosphorylated at T1989.

• Possibility to establish stable and effective immunoassays to select drugs specifically targeting ATR.

• Works in western blot and IFA applications on crude (unenriched) cell lysates.

• Works in standard processed clinical and preclinical samples.

• Can be used to report drug activity.

Development Stage:

• In vitro data available

• In vivo data available (animal)

• Prototype

Inventors: Thomas D. Pfister (SAIC-Frederick), Allison M. Marrero (SAIC-Frederick), Ralph E. Parchment (SAIC-Frederick), James H. Doroshow (NCI)

Intellectual Property: HHS Reference No. E-001-2014/0 - US Provisional Application No. 61/893,070 filed 18 Oct 2013

Licensing Contact: Surekha Vathyam, Ph.D.; 301-435-4076; vathyams@mail.nih.gov

Monitoring the Effects of Sleep Deprivation Using Neuronal Avalanches

Description of Technology: Investigators at the National Institute of Mental Health have discovered a novel method for monitoring the effects of sleep deprivation on brain activity. Sleep deprivation has been known to adversely affect basic cognitive abilities, such as object recognition and decision making, even leading to hallucinations and epileptic seizures. This invention measures the degree of sleep deprivation and decrease in behavioral performance directly from resting brain activity. A deviation from optimal avalanche parameters correlates with duration of wakefulness and decrease in performance.

Potential Commercial Applications:

• Monitor wakefulness, reaction time

• Potential application for monitoring sleep-deprived first-responders (e.g., military, EMT, etc.)

Competitive Advantages:

• Continuously monitors brain activity

• Non-invasive

Development Stage:

• In vivo data available (human)

• Prototype

Inventors: Dietmar Plenz (NIMH), Oren Shriki (NIMH), Christian Meisel (NIMH), Giulio Tononi (Univ. Wisconsin)

Publication: Meisel C, et al. Fading signatures of critical brain dynamics during sustained wakefulness in humans. J Neurosci. 2013 Oct 30;33(44):17363-72. [PMID 24174669]

Intellectual Property: HHS Reference No. E-345-2013/0 - US Application No. 61/866,962 filed 16 Aug 2013

Related Technologies: HHS Reference No. E-294-2005/1 -

• US Application No. 11/990,419 filed 14 Aug 2006, which issued as US Patent No. 8,548,786 on 01 Oct 2013

• CA Application No. 2,618,933 filed 14 Aug 2006

• AU Application No. 2006279572 filed 14 Aug 2006

• EP Application No. 06813476.6 filed 14 Aug 2006

• JP Application No. 2008-526298 filed 14 Aug 2006

• AU Application No. 2013201187 filed 14 Aug 2006

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

Collaborative Research Opportunity: The National Institute of Mental Health 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 Suzanne Winfield, Ph.D. at winfiels@mail.nih.gov.

Simple Biosensors Based on Electrical Percolation Biological Semiconductors

Description of Technology: The invention offered for licensing is in the field of biosensors with application in diagnostics and in regulation of implantable biomedical devices. More specifically, it is related to biological semiconductors based on the electrical percolation of single-walled carbon nanotubes (SWNTs). The nanotubes are embedded with biological ligands (e.g., antibodies). The electrical resistance of a semiconducting SWNT is found to dramatically increase upon the actuation by a specific antigen. Measurement of the change in resistance correlates with the concentration of the specific antigen and thus provides for quantitative determination and diagnostics of biological samples. The simple printing fabrication of electrical percolation biological semiconductors (EPBSC) can facilitate assembly of numerous types of gates (e.g., antibodies, DNA, etc.) and print many of such gates on the same chip for the creation of biological CPUs for various biomedical applications, including direct biodetection and regulation of implantable biomedical devices.

Potential Commercial Applications:

• Pathogen detection

• Biomarker targeted diagnostics

• Point-of-care

• Food allergens

Competitive Advantages:

• Easy to assemble

• Detection of multiple analytes

• Digital signal amplification

• Stable shelf-life

Development Stage:

• In vitro data available

• Prototype

Inventors: Avraham Rasooly (NCI), Minghui Yang (Univ. of Maryland, Baltimore), Yordan Kostov (Univ. of Maryland, Baltimore), Hugh Brock (Univ. of Maryland, College Park)

Publications:

1. Qu F, et al. Electrochemical biosensing platform using hydrogel prepared from ferrocene modified amino acid as highly efficient immobilization matrix. Anal Chem. 2014 Jan 21;86(2):973-6. [PMID 24383679]

2. Herold KE, Rasooly A. Editorial for "biosensor technologies". Methods. 2013 Oct;63(3):201. [PMID 24139786]

3. Bruck HA, et al. Electrical percolation based biosensors. Methods. 2013 Oct;63(3):282-9. [PMID 24041756]

4. Balsam J, et al. Thousand-fold fluorescent signal amplification for mHealth diagnostics. Biosens Bioelectron. 2014 Jan 15;51:1-7. [PMID 23928092]

5. Rasooly A, et al. An ELISA Lab-on-a-Chip (ELISA-LOC). Methods Mol Biol. 2013;949:451-71. [PMID 23329460]

Intellectual Property: HHS Reference No. E-040-2009/0 -

• US Patent No. 8,614,466 issued 24 Dec 2013

• Pending European Patent Application 09828144.7

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

Viral Like Particles Based Chikungunya Vaccines

Description of Technology: Chikungunya virus (CHIKV) is mosquito-borne alphavirus endemic in Africa, India, and Southeast Asia. In 2013 CHIKV infection has also emerged in the Caribbean and a pandemic of CHIKV has re-emerged in the Philippines following Typhoon Haiyan. Currently, there is no vaccine available for the prevention of CHIKV infection and no specific therapy exists to treat the illness. Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) have developed a CHIKV Viral Like Particle (CHIKV VLP) vaccine based on plasmid expression vectors encoding structural proteins of the CHIKV virus, which gave rise to CHIKV VLPs in transfected cells. The CHIKV VLPs consist of the core, E1 and E2 proteins and are similar in buoyant density and morphology to replication-competent CHIKV virus. Immunization with CHIKV VLPs elicited neutralizing antibodies against envelope proteins from different CHIKV strains in

mouse and nonhuman primate (NHP) models. Monkeys immunized with CHIKV VLPs produced high titer neutralizing antibodies that protected against viremia after high dose challenge. The selected CHIKV VLP vaccine candidate, VRC-CHKVLP059-00-VP, composed of the E1, E2, and capsid proteins from the CHIKV strain 37997, was recently evaluated by the VRC at the NIH Clinical Center for safety, tolerability and immunogenicity in the clinical protocol VRC 311 (ClinicalTrials.gov # NCT01489358), a Phase I, open-label, dose escalation clinical trial. The VRC-CHKVLP059-00-VP vaccine was highly immunogenic, safe, and well-tolerated. VRC researchers have also developed the transient transfection manufacturing process for CHIKV and other alphaviruses, such as Western, Eastern and Venezuelan Equine Encephalitis (WEVEE) viruses. Pre-clinical in vivo mouse and NHP data, Phase 1 clinical trial data and manufacturing data are available.

NIH will evaluate a license applicant's capabilities and experience in advancing similar technologies through the regulatory process. This technology is not eligible for the NIH's start-up license program.

Potential Commercial Applications: Chikungunya vaccines based on viral like particles.

Competitive Advantages:

• There is currently no CHIKV vaccine on the market.

• VRC-CHKVLP059-00-VP vaccine candidate is highly immunogenic, safe, and well-tolerated.

• Minimal containment requirements for CHIKV VLP manufacturing because live virus production is not required.

Development Stage:

• In vitro data available

• In vivo data available (animal)

• In vivo data available (human)

Inventors: Gary J. Nabel, Wataru Akahata, Srinivas S. Rao (all of VRC/NIAID)

Publications:

1. Akahata W, et al. A virus-like particle vaccine for epidemic Chikungunya virus protects non-human primates against infection. Nat Med. 2010 Mar;16(3):334-8. [PMID 20111039]

2. Akahata W, Nabel GJ. A specific domain of the Chikungunya virus E2 protein regulates particle formation in human cells: implications for alphavirus vaccine design. J Virol. 2012 Aug;86(16):8879-83. [PMID 22647698]

3. Chang et al. Chikungunya Virus-Like Particle Vaccine Elicits Neutralizing Antibodies in Healthy Adults in a Phase I Clinical Trial; manuscript submitted.

Intellectual Property:

HHS Reference Nos. E-004-2009/0 /1 /2 –

• US Provisional Application No. 61/118,206 filed 26 Nov 2008

• US Provisional Application No. 61/201,118 filed 05 Dec 2008

• International Application No. PCT/US2009/006294 (WO 2010/062396) filed 24 Nov 2009

• and corresponding filings in the US, Europe, China, Australia, Brazil, India, Malaysia, South Africa, Singapore, Indonesia, Philippines and Vietnam

HHS Reference Nos. E-057-2011/0 /1 /2 –

• US Provisional Application No. 61/438,236 filed 31 Jan 2011

• International Application No. PCT/US2012/023361 (WO 2012/106356) filed 31 Jan 2012

• and corresponding filings in the US and India

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., MBA; 301-435-4507; ThalhamC@mail.nih.gov

Dated: August 20, 2014.

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

Billing Code 4140-01-P

[FR Doc. 2014-20183 Filed 08/25/2014 at 8:45 am; Publication Date: 08/26/2014]