This document is scheduled to be published in the
Federal Register on 07/19/2013 and available online at
http://federalregister.gov/a/2013-17319, and on **FDsys.gov**

[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.

Use of Cysteamine to Treat Metastatic Cancer

Description of Technology: Cysteamine is an aminothiol and anti-oxidant that has potential for the treatment of radiation sickness, neurological disorders and cancer. Cysteamine has FDA approval for use in humans, and produces few side-effects as a natural degradation product of an essential amino acid. It is mostly used for treatment of cystinosis. The inventors on this technology have demonstrated that cysteamine also suppresses the activity of matrix metalloproteinases (MMPs). Because MMPs have been implicated in tumor invasion and metastasis, cysteamine has potential as an effective therapeutic for metastatic cancer. Administration of cysteamine was able to reduce invasion and metastasis in mouse xenograft tumor models and prolong survival of the mice without significant adverse side effects. This suggests that cysteamine could represent a novel therapeutic agent for treatment of metastatic cancer.

Potential Commercial Applications: Therapeutic for metastatic cancer as monotherapy or combined with other drugs.

Competitive Advantages:

• Cysteamine does not produce adverse side-effects when administered to humans.

• Cysteamine has already been approved for use in humans, providing a clearer path to clinical approval.

Development Stage:

• Pre-clinical

• In vitro data available

• In vivo data available (animal)

Inventors: Raj K. Puri and Bharat Joshi (CBER/FDA)

Publication: Fujisawa T, et al. Cysteamine suppresses invasion, metastasis and prolongs survival by inhibiting matrix metalloproteinases in a mouse model of human pancreatic cancer. PLoS One. 2012;7(4):e34437. [PMID 22532830]

Intellectual Property: HHS Reference No. E-219-2013/0 –

• US Provisional Application No. 61/814,010

• Canadian Application No. 2813514

• Australian Application No. 2013205350

• Korean Application No. 10-2013-43713

Licensing Contact: David A. Lambertson, Ph.D.; 301-435-4632; lambertsond@mail.nih.gov

Encircling Suture Delivery System

Description of Technology: The invention provides a novel delivery system for delivering an encircling suture which includes two separate hollow limbs held together at an articulation by the suture to be delivered. The suture can extend through the hollow limbs, which slide along the suture. The distal ends of the limbs can be compressed into a desired delivery shape that allows the limbs to be advanced through the lumen of a delivery catheter (e.g., a transcutaneous, transvascular or intraluminal catheter) into any body cavity. As the distal portions of the limbs move out of the delivery catheter, the limbs cooperatively assume a loop shape complementary to the shape of the target around the encircling suture to leave only the suture in the desired delivery position while

maintaining desired suture tension and position. The delivery device can be placed around a variety of anatomical structures (e.g., heart, arterial appendage, cecal appendix, gall bladder, neoplasm, uterus, hemorrhoid, uvula, aneurysm, transected blood vessel, folded or looped lumen, intraocular crystalline lens or implated intraocular lens or haptic, urinary bladder, kidney, prostate, intestine, or liver, etc.).

Potential Commercial Applications:

• Surgery

• Suturing

• Catheterization

• Cardiac valve repair

Competitive Advantages:

• Formable suturing

• Circumferential suturing

• Flexible

• Easy to use

Development Stage: Prototype

Inventors: Toby Rogers, Robert Lederman, Merdim Sonmez, Dominique Franson, Ozgur Kocaturk (all of NHLBI)

Intellectual Property: HHS Reference No. E-115-2013/0 – US Provisional Patent Application 61/834,357 filed June 12, 2013

Related Technologies:

• HHS Reference No. E-027-2013/0 – Devices and Methods for Treating Functional Tricuspid Valve Regurgitation

• HHS Reference No. E-112-2010/0 – Target and Capture Device for Transcatheter Cerclage Annuloplasty

• HHS Reference No. E-108-2010/0 – An Expandable Mesh Target and Capture Device for Transcatheter Cerciage Annuloplasty

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

Peptide Inhibitors of Polo-like Kinase 1 (PLK1) Useful as Anti-cancer Therapeutics

Description of Technology: PLK1 is being studied as a target for cancer drugs. Many colon and lung cancers are caused by KRAS mutations. These cancers are dependent on PLK1. Inhibition of PLK1 allows for selective killing of cancer cells without harm to normal cells. The peptide derivatives available for licensing have achieved both good efficacy and enhanced bioavailability.

Potential Commercial Applications: Development of selective cancer therapeutics.

Competitive Advantages: Enhanced bioavailability and higher binding efficacy over existing peptide PLK1 ligands.

Development Stage: Early-stage.

Inventors: Terrence R. Burke, Fa Liu, Wen-Jian Qian, Jung-Eun Park, Kyung S. Lee (all of NCI)

Publications:

1. Liu F, et al. Serendipitous alkylation of a Plk1 ligand uncovers a new binding channel. Nat Chem Biol. 2011 Jul 17;7(9):595-601. [PMID 21765407]

2. Qian W, et al. Investigation of unanticipated alkylation at the N(π) position of a histidyl residue under Mitsunobu conditions and synthesis of orthogonally protected histidine analogues. J Org Chem. 2011 Nov 4;76(21):8885-90. [PMID 21950469]

3. Liu F, et al. Identification of high affinity polo-like kinase 1 (Plk1) polo-box domain binding peptides using oxime-based diversification. ACS Chem Biol. 2012 May 18;7(5):805-10. [PMID 22292814]

4. Liu F, et al. Peptoid-Peptide hybrid ligands targeting the polo box domain of polo-like kinase 1. Chembiochem. 2012 Jun 18;13(9):1291-6. [PMID 22570300]

5. Qian W, et al. Effects on polo-like kinase 1 polo-box domain binding affinities of peptides incurred by structural variation at the phosphoamino acid position. Bioorg Med Chem. 2013 Jul 15;21(14):3996-4003. [PMID 22743087]

6. Qian W, et al. Non-proteinogenic amino acids in the pThr-2 position of a pentamer peptide that confer high binding affinity for the polo box domain (PBD) of polo-like kinase 1 (Plk1). Bioorg Med Chem Lett. 2012 Dec 15;22(24):7306-8. [PMID 23159568]

Intellectual Property: HHS Reference No. E-094-2013/0 – US Application No. 61/784,971 filed March 14, 2013

Related Technologies: HHS Reference Nos. E-181-2009/0, E-181-2009/1, E-181-2009/3, E-181-2009/4, E-053-2012/0 – Development of Peptide Mimetic Ligands of Polo-like Kinase 1 Polo Box Domain

Licensing Contact: Patrick McCue, Ph.D.; 301-435-5560; mccuepat@mail.nih.gov

Polymeric Silicone Hydrogel Vessel Mimetics for Cell Culturing

Description of Technology: The invention pertains to high oxygen diffusivity silicone hydrogel support structures that mimic tissue vasculature (e.g., capillary bed). Photolithographic methods are used to construct mimetic silicone hydrogel pillars that have, for example, a 20:1 height to diameter ratio. Advantageously, these mimetic silicone hydrogels diffuse oxygen from the bottom chamber to the cells cultured on the surface at near physiological rates (60 times that of water). Uses of these mimetics include 2-D screening for chemotherapeutic compounds and growth of tissue for grafting.

Potential Commercial Applications:

• Tissue engineering

• Simulation of physiological growth conditions

Competitive Advantages: High oxygen diffusivity

Development Stage:

• Prototype

• Pilot

• In vitro data available

Inventors: Chandan Das (NCI), Ashley Jaeger (CIT), Thomas Pohida (CIT), Randall Pursley (CIT), Philip McQueen (CIT), Nicole Morgan (NIBIB), Michael Gottesman (NCI)

Intellectual Property:

• HHS Reference No. E-070-2013/0 – US Provisional Patent Application 61/758,198 filed January 29, 2013

• HHS Reference No. E-070-2013/1 – US Provisional Patent Application 61/773,064 filed March 5, 2013

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

Co-Transcriptional Assembly of Modified RNA Nanoparticles

Description of Technology: A method is provided for generating RNA nanoparticles having modified nucleotides and/or having increased nuclease resistance where the RNA nanoparticles are formed co-transcriptionally by T7 RNA polymerase in the presence of manganese ions.

Potential Commercial Applications: Inexpensive and efficient method of producing chemically modified RNA nanoparticles for diagnostic or therapeutic applications.

Competitive Advantages:

• Overcomes the cost and size limitations of solid-phase RNA synthesis.

• Allows complexity of RNA nanoparticles production.

• Increases retention time of RNA nanoparticles.

Development Stage:

• Early-stage

• In vitro data available

Inventors: Bruce A. Shapiro (NCI), Kirill Afonin (NCI), Maria Kireeva (NCI), Mikhail Kashlev (NCI), Luc Jaeger (Univ California, Santa Barbara), Wade Grabow (Univ California, Santa Barbara)

Publications:

1. Afonin KA, et al. Co-transcriptional assembly of chemically modified RNA nanoparticles functionalized with siRNAs. Nano Lett. 2012 Oct 10;12(10):5192-5. [PMID 23016824]

2. Grabow WW, et al. "RNA Nanotechnology in Nanomedicine," in Nanomedicine and Drug Delivery (Recent Advances in Nanoscience and Nanotechnology), ed. M Sebastian, et al. (New Jersey: Apple Academic Press, 2012), 208-220. [Book Chapter]

3. Shukla GC, et al. A boost for the emerging field of RNA nanotechnology. ACS Nano. 2011 May 24;5(5):3405-18. [PMID 21604810]

4. Afonin KA, et al. Design and self-assembly of siRNA-functionalized RNA nanoparticles for use in automated nanomedicine. Nat Protoc. 2011 Dec 1;6(12):2022-34. [PMID 22134126]

5. Bindewald E, et al. Multistrand RNA secondary structure prediction and nanostructure design including pseudoknots. ACS Nano. 2011 Dec 27;5(12):9542-51. [PMID 22067111]

6. Grabow WW, et al. Self-assembling RNA nanorings based on RNAI/II inverse kissing complexes. Nano Lett. 2011 Feb 9;11(2):878-87. [PMID 21229999]

7. Kasprzak W, et al. Use of RNA structure flexibility data in nanostructure modeling. Methods. 2011 Jun;54(2):239-50. [PMID 21163354]

Intellectual Property: HHS Reference No. E-223-2012/0 – US Provisional Application No. 61/698,227 filed 07 Sep 2012

Related Technologies:

• HHS Reference No. E-059-2009/0 – International Application No. PCT/US2010/038818

• HHS Reference No. E-038-2012/0 – International Application No. PCT/US2012/065932

• HHS Reference No. E-039-2012/0 – International Application No. PCT/US2012/065945

Licensing Contact: John Stansberry; 301-435-5236; stansbej@mail.nih.gov

Collaborative Research Opportunity: The NCI Center for Cancer Research Nanobiology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize diagnostic or therapeutic RNA nanoparticles. For collaboration opportunities, please contact John Hewes, Ph.D. at hewesj@mail.nih.gov.

July 12, 2013
Date

Richard U. Rodriguez,
Director
Division of Technology Development and Transfer
Office of Technology Transfer
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[FR Doc. 2013-17319 Filed 07/18/2013 at 8:45 am; Publication Date: 07/19/2013]