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Registration: Registration is limited and is available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. (EDT), October 10, 2013. Onsite registration will be available after this date. To register for the public workshop, please visit AGA's Web site at <http://www.gastro.org/education-meetings/live-meetings/aga-fda-regulation-and-reimbursement-workshop>. For more information on the workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

The AGA will collect a registration fee to cover its share of the expenses associated with the public workshop, which is included in the registration information on the AGA Web site.

If you need special accommodations due to a disability, please contact Herbert Lerner (see "*Contact Person*") at least 7 days before the public workshop.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the public workshop is to facilitate discussion between FDA, the AGA and other interested parties on the issues of device development, public and private payer reimbursement, venture capital, and regulatory pathways for device innovation and marketing. The workshop will provide a forum for discussing new approaches for the treatment of morbid obesity and other metabolic diseases as well as evolving approaches for the regulation and reimbursement of minimally invasive procedures.

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to:

- Challenges to MedTech Innovation in the United States;
- Evolving Approaches for the Regulation of Minimally Invasive Procedures: The FDA Benefit/Risk Paradigm;
- Evolving Approaches for the Reimbursement of Minimally Invasive

Procedures: How to Put a Price on Value;

- Obesity as a Disease: Redefining the Regulatory and Reimbursement Context; and

- The "Process"—Investigational Device Exemption Review.

Dated: September 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-22311 Filed 9-12-13; 8:45 am]

BILLING CODE 4160-01-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 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.

Aortic Access From Vena Cava for Large Caliber Transcatheter Cardiovascular Interventions

Description of Technology: The invention pertains to a device and method for transcatheter correction of cardiovascular abnormalities, such as the delivery of prosthetic valves to the heart. Featured is a device implant for closing a caval-aortic iatrogenic fistula created by the introduction of a transcatheter device from the inferior vena cava into the abdominal aorta. The occlusion device includes an expandable transvascular implant with an elastomeric surface capable of extending between a vein and artery

which conforms to the boundaries of an arteriovenous fistula tract between the artery and vein. A guidewire channel is disposed within the occlusion device where the channel also has elastomeric wall surfaces that conform or can be expanded to the area so that it occludes the channel when the guidewire is not present. The implant is resiliently deformable into a radially compressed configuration for delivery through the catheter. When not deformed into the radially compressed configuration, the distal end of the device is radially enlarged, relative to the intermediate neck, whereby the distal end forms an enlarged distal skirt, such as a disk or button shaped member. A polymer coating on the radially enlarged distal end conforms to the endoluminal aortic wall for deployment against an internal wall of the artery.

Potential Commercial Applications:

- cardiovascular surgery.
 - heart valve implantation.
 - valve-repair.
- Competitive Advantages:*
- closure of the caval-aortic iatrogenic fistula.
 - vascular access.
- Development Stage:*
- Prototype.
 - In vivo data available (animal).
 - In vivo data available (human).

Inventors: Robert Lederman and Ozgur Kocaturk (NHLBI).

Publications:

1. Kodali SK, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. *N Engl J Med.* 2012 May 3;366(18):1686-95. [PMID 22443479]
2. Makkar RR, et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. *N Engl J Med.* 2012 May 3;366(18):1696-704. [PMID 22443478]
3. Smith CR, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med.* 2011 Jun 9;364(23):2187-98. [PMID 21639811]

Intellectual Property: HHS Reference No. E-553-2013/0—U.S. Provisional Patent Application 61/863,071 filed August 7, 2013.

Related Technologies:

- HHS Reference No. E-115-2013/0—U.S. Provisional Patent Application No. 61/834,357 filed June 12, 2013.
 - HHS Reference No. E-027-2013/0—U.S. Provisional Patent Application No. 61/785,652 filed March 14, 2013.
- Licensing Contact:* Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity: The National Heart Lung & Blood

Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Transcatheter Cardiovascular Interventions. For collaboration opportunities, please contact Ms. Peg Koelble at koelblep@mail.nih.gov or 301-402-5579.

Photoactivatable Nanoparticles for Targeted Drug Delivery

Description of Technology: The invention relates to novel lipid-based nanoparticles (liposomes) for use in targeted drug delivery. The particles include a wall surrounding a cavity, wherein the wall includes (i) a lipid bilayer comprising 1,2-bis(tricoso-10,12-diynoyl)-sn-glycero-3-phosphocholine (DC8,9PC), and dipalmitoylphosphatidylcholine (DPPC), and (ii) a tetrapyrrolic photosensitizer, such as 2-[1-hexyloxyethyl]-2-devinyl pyropheophorbide-a (HPPH) within the lipid bilayer. The lipid bilayer may include one or more segregated regions, or pockets, of DC8,9PC with the HPPH being preferentially located within the DC8,9PC pockets. The nanoparticles include at least one therapeutic agent within the cavity. Upon a targeted application of light in the near-infrared range, the particles are disrupted and can release the therapeutic agent at a targeted site. The concurrent release of the photosensitizing agent HPPH may be advantageous in the treatment of certain cancers, since this agent has shown to possess therapeutic ability on its own right.

Potential Commercial Applications: The nanoparticles can be used for targeted drug delivery.

Competitive Advantages:

- The particles are stable and can be activated upon demand to release the therapeutic agent at the desired site.
- The concurrent release of the photosensitizing agent HPPH may be advantageous in the treatment of certain types of cancer, since this agent has shown to possess therapeutic ability on its own right.

Development Stage: In vivo data available (animal).

Inventors: Anu Puri (NCI) et al.

Publications:

1. Yavlovich A, et al. Design of liposomes containing photopolymerizable phospholipids for triggered release of contents. *J Therm Anal Calorim.* 2009 Oct1;98(1):97-104. [PMID 20160877]
2. Yavlovich A, et al. A novel class of photo-triggerable liposomes containing DPPC:DC(8,9)PC as

vehicles for delivery of doxorubicin to cells. *Biochim Biophys Acta.* 2011 Jan;1808(1):117-26. [PMID 20691151]

3. Puri A, Blumenthal R. Polymeric lipid assemblies as novel theranostic tools. *Acc Chem Res.* 2011 Oct 18;44(10):1071-9. [PMID 21919465]
4. Puri A, et al. Material properties of matrix lipids determine the conformation and intermolecular reactivity of diacetylenic phosphatidylcholine in the lipid bilayer. *Langmuir.* 2011 Dec 20;27(24):15120-8. [PMID 22053903]

Intellectual Property: HHS Reference No. E-482-2013/0—U.S. Application No. 61/845,861 filed July 12, 2013.

Related Technologies:

1. Fabrication of phototriggerable liposomes.
2. Loading of a drug into the cavity and HPPH in the lipid bilayer of liposomes.
3. Laser-triggered release in vitro and in tumors.

Licensing Contact: Uri Reichman, Ph.D., MBA; 301-435-4616; ur7a@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 photoactivatable nanoparticles for drug delivery. For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

Signatures of Genetic Control in Digestive and Liver Disorders

Description of Technology: Our technology describes unique genetic signatures in patients with digestive diseases and liver disorders. Using comprehensive analysis of 735 microRNAs and 19,000 mRNAs, we have identified a unique set of microRNAs and/or mRNAs which predict disease phenotypes in patients with digestive and liver disorders. The identification of such point-of-care genetic signatures is significant for both personalized biomarkers and novel targeted biotherapeutics. These microRNAs and mRNAs function either together or separately thus modulating protein expressions in one or more signaling pathways. A particular noteworthy signature of genetic control includes miR-150, which is known to modulate target proteins within the Akt signaling pathways implicated in inflammatory processes as well as processes affecting cancer cell proliferation and/or survival.

Potential Commercial Applications:

- Personalized biomarkers.
 - Novel targeted biotherapeutic.
- Competitive Advantages:*
- Point-of-care signatures from minimally invasive samples.
 - Protocol streamlined for high-throughput analysis.
 - Quantitative molecular diagnostics.
 - Unique microRNAs and/or mRNAs reveal biological targets within synergistic cellular pathways.
- Development Stage:*
- Pilot.
 - Early-stage.
 - Pre-clinical.
 - In vitro data available.

Inventors: Wendy A. Henderson, Ralph M. Peace, Nicolaas H. Fourie, Sarah K. Abey (NINR).

Intellectual Property:

- HHS Reference No. E-349-2013/0—U.S. Provisional Patent Application No. 61/825,154 filed May 20, 2013.
- HHS Reference No. E-349-2013/1—U.S. Provisional Patent Application No. 61/825,489 filed May 20, 2013.

Licensing Contact: Suryanarayana (Sury) Vepa, Ph.D., J.D.; 301-435-5020; vepas@mail.nih.gov.

Histone Deacetylase (HDAC) Inhibitors That Enhance Chemotherapy

Description of Technology: In cancers with KRAS-mutations, such as leukemias, colon cancer, pancreatic cancer, and lung cancer, researchers at the NCI have observed that administration of the HDAC inhibitor romidepsin in combination with certain MAPK pathway and PI3K pathway inhibitors resulted in significant cytotoxicity, regardless of the type of cancer. Further, the researchers have achieved this effect at clinically relevant dosages and time periods.

Available for licensing are methods that employ these findings to treat cancers or induce cell death in tumor cells.

Potential Commercial Applications: Development of therapeutics for cancers with a high instance of KRAS mutations such as leukemias, colon cancer, pancreatic cancer, and lung cancer.

Competitive Advantages: The synergistic combination of agents induces cytotoxicity better than any of the agents alone.

Development Stage: Early-stage.

Inventors: Susan E. Bates, et al. (NCI).

Intellectual Property: HHS Reference No. E-097-2013/0—U.S. Application No. 61/807,574 filed April 2, 2013.

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

Dipicolylamine-based Nanoparticles for Delivery of Ligands

Description of Technology: Many potential nucleic acid therapeutics have not transitioned from the research laboratory to clinical application in large part because delivery technologies for these therapies are not effective. Most nucleic acid delivery technologies are lipid-based or positively charged and require chemical or physical conjugation with the nucleic acid. These delivery systems are often therapeutically unacceptable due to toxicity or immune system reactivity. The present technology is a nanoparticle complex, containing a polymer substrate, such as a hyaluronic acid, and Zn²⁺-dipicolylamine (Zn-DPA), that associates selectively with the nucleic acid phosphodiester groups. This complex functions as a simple, easy to scale-up, cost effective, low toxicity delivery system for potential nucleic acid therapeutics, such as siRNA molecules. It may also be capable of co-delivering other small molecule drugs.

Potential Commercial Applications:

- Drug delivery.
- Gene therapy.

Competitive Advantages:

- Efficient.
- Easy to scale-up.
- Cost effective
- Low toxicity

Development Stage:

- Early-stage
- In vivo data available (animal)

Inventors: Xiaoyuan Chen (NIBIB), Seulki Lee (NIBIB), KiYoung Choi (NIBIB), Gang Liu (North Sichuan Medical College, China).

Publication: Liu G, et al. Sticky nanoparticles: a platform for siRNA delivery by bis(zinc(II) dipolyamine)-functionalized, self-assembled nanoconjugate. *Angew Chem Int Ed Engl.* 2012 Jan 9;51(2):445–9. [PMID 22110006].

Intellectual Property: HHS Reference No. E-066–2012/0—U.S. Provisional Application No. 61/729,159 filed November 21, 2012

Licensing Contact: Edward (Tedd) Fenn; 424–500–2005; tedd.fenn@nih.gov.

Collaborative Research Opportunity: The National Institute of Biomedical Imaging and Bioengineering 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 Henry S. Eden, M.D., Ph.D. at edenh@mail.nih.gov.

Norovirus-Neutralizing Monoclonal Antibodies

Description of Technology: Vaccines and therapies to prevent and treat Norovirus infections do not exist, despite the worldwide prevalence of Norovirus infections. Outbreaks of human gastroenteritis attributable to Norovirus commonly occur in group setting, such as hospitals, nursing homes, schools, dormitories, cruise ships and military barracks.

This technology relates to monoclonal antibodies, which specifically bind to Norovirus and have therapeutic potential. In a primate model, these antibodies stimulated a strong adaptive immune response which may produce a protective effect. These Norovirus antibodies may have application as immunoprophylaxis to protect individuals from infections or as a possible treatment for infected individuals.

Potential Commercial Applications:

- Therapeutic
- Vaccine

Competitive Advantages: Currently, no vaccines or therapies exist to prevent and treat Norovirus infections.

Development Stage:

- Early-stage
 - In vivo data available (animal)
- Inventors:* Zhaochun Chen, Robert H. Purcell, Lisbeth Kim Green, Stanislav Sosnovtsev, Karin Bok (all of NIAID).

Publication: Chen Z, et al.

Development of Norwalk virus-specific monoclonal antibodies with therapeutic potential for the treatment of Norwalk virus gastroenteritis. *J Virol.* 2013 Sep;87(17):9547–57. [PMID 23785216].

Intellectual Property: HHS Reference No. E-226–2011/0—U.S. Provisional Application No. 61/763,879 filed February 2, 2013.

Licensing Contact: Edward (Tedd) Fenn; 424–500–2005; tedd.fenn@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases 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 Maryann Puglielli, Ph.D., J.D. at pugliellim@mail.nih.gov.

Dated: September 9, 2013.

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

[FR Doc. 2013–22264 Filed 9–12–13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5681–N–37]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT:

Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION:

In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v. Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where