discusses methods of detecting DILI by periodic tests of serum enzyme activities and bilirubin concentration, and how changes in the results of those laboratory tests over time, along with symptoms and physical findings, may be used to estimate severity of the injury. It suggests some ''stopping rules'' for interrupting drug treatment, and the need to obtain sufficient clinical information to assess causation. FDA published a draft of this guidance in 2006, and comments on the draft were taken into consideration when issuing the final guidance in July 2009 (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM174090.pdf*.). FDA is now interested in obtaining stakeholder input on the issues addressed in this guidance, including comments regarding potential revisions to the guidance.

II. The Public Conference

A. Why are we holding this conference?

The purpose of the 2013 conference is to invite participants to present their data and views, and to hold open discussion.

B. Registration, Transcripts, and Additional Information on This Conference and Its Predecessors

A registration fee ($600 for industry registrants and $300 for Federal Government and academic registrants) will be charged to help defray the costs of renting meeting spaces and the meals and snacks provided. The fee will also be used to cover travel costs incurred by invited academic (but not Government or Industry) speakers and other expenses. The registration process will be handled by C-Path, an independent, nonprofit organization established in 2005 with public and private philanthropic support from the southern Arizona community, Science Foundation Arizona, and FDA.

The presentations and discussions will be transcribed and published on the Internet for public availability after minor editing by the organizers of the meeting.

Additional information on the conference, program, and registration procedures may be obtained on the Internet at *http://www.c-path.org*, and also at *http://www.fda.gov* by typing into the search box ''liver toxicity''. (FDA has verified the C-Path Web site address, but is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) Material presented at past programs (from 1999 to 2012) may be accessed at *www.aasld.org*. Click on Education/Training and then scroll down to ''Drug Induced Liver Injury 2012 Program.''

Dated: January 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01640 Filed 1–25–13; 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, 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.

SIRT2 Inhibitors as Novel Therapeutics for Myocardial Infarction and Ischemic Stroke and to Prevent Necrosis

Description of Technology: Sirtuin 2 (SIRT2) inhibitors to reduce necrosis and, thereby, as novel therapeutics to treat ischemic stroke and myocardial infarction. Accumulating evidence indicates that programmed necrosis plays a critical role in cell death during ischemia-reperfusion. NIH investigators have shown that the NAD-dependent deacetylase SIRT2 binds constitutively to receptor-interacting protein 3 (RIP3) and that deletion or knockdown of SIRT2 prevents formation of the RIP1–RIP3 complex in mice. These investigators also found that genetic or pharmacological inhibition of SIRT2 blocks cellular necrosis induced by TNF-alpha and RIP1 is a critical target of SIRT2-dependent deacetylation. Further studies also showed that the hearts of *Sirt2*$^{-/-}$ mice, or wild-type mice treated with a specific pharmacological inhibitor of SIRT2, show marked protection from ischemic injury. These results implicate SIRT2 as an important regulator of programmed necrosis and indicate that SIRT2 inhibitors may constitute a novel approach to protect against necrotic injuries, including ischemic stroke and myocardial infarction.

Potential Commercial Applications:

- Novel therapeutics to protect against necrotic injuries.
- Novel therapeutics to treat ischemic stroke and myocardial infarction.
- Novel therapeutics to treat diseases in which necrosis is involved.

Competitive Advantages:

- None of the currently available drugs address the necrotic damage caused due to ischemia and reperfusion.
- Using a SIRT2 inhibitor could limit the damage caused by necrosis and contribute to accelerated recovery in patients suffering from these conditions.

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Drs. Nisha Narayan and Toren Finkel (NHLBI)

Publication: Narayan N, et al. The NAD-dependent deacetylase SIRT2 is required for programmed necrosis. Nature. 2012 Dec 13;492(7428):199–204. [PMID 23201684]

Intellectual Property: HHS Reference No. E–003–2013/0—U.S. Application No. 61/723,496 filed 17 Nov 2012

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

Collaborative Research Opportunity: The NHLBI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize retinoid-related orphan receptors (RORs) function in chronic diseases. For collaboration opportunities, please contact Ms. Peg Koelble at *koelblep@mail.nih.gov* or 301–594–4095.

Multivalent Meningiococcal Conjugates and Methods for Preparing Conjugates

Description of Technology: Among 13 isolated meningococcal serogroups, A, B, C, W–135 and Y are the most prevalent. There are three FDA-approved capsular polysaccharide (PS)-based vaccines, one tetravalent PS vaccine, and two tetravalent conjugate vaccines for protection against

meningococcal disease caused by groups A, C, W–135 and Y Neisseria meningitidis. Group B capsular PS is similar to the PS structure expressed in certain human tissues, thus making it a poor immunogen. Furthermore, if used as a vaccine, the possibility exists of it inducing an autoimmune response. Thus, a need remains to develop additional meningococcal vaccines, particularly for group B and group X meningococcal serogroups.

This application claims immunogenic conjugates including at least one polysaccharide conjugated to a group B factor H binding protein (fHbp). Also claimed are immunogenic conjugates including at least one polysaccharide conjugated to a Neisserial surface protein A (NspA). Additionally, improved methods for preparing conjugates are claimed.

Potential Commercial Applications:
- Multivalent meningitis vaccine
- Research tool

Competitive Advantages:
- Higher vaccine yield
- More efficient conjugation method
- Lower cost vaccines

Development Stage:
- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Che-Hung Robert Lee (FDA/CBER), Vavlerian Pinto (EM), Elizabeth Moran (EM), Robert Burden (EM)

Intellectual Property: HHS Reference No. E–082–2012/0—U.S. Application No. 61/651,382 filed 24 May 2012.

Related Technologies:
- HHS Reference No. E–301–2003/0—U.S. Application No. 13/243,480 filed 06 Aug 2004, claiming priority to 06 Aug 2003
- HHS Reference No. E–085–2005/0—U.S. Patent 8,173,135 issued 08 May 2012; U.S. Application No. 13/440,856 filed 05 Apr 2012, claiming priority to 17 Mar 2006

Licensing Contact: Peter A. Soukas; 301–435–4646; ps193c@nih.gov

Collaborative Research Opportunity: The FDA/CBER is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Multivalent Meningiococcal Conjugates and Methods for Preparing Conjugates. For collaboration opportunities, please contact Che-Hung Robert Lee at *robert.lee@fda.hhs.gov* or 301–451–5934.

Enhanced Cancer Therapy Using Photoimmunotherapy (PIT) in Combination With Anti-Cancer Agents

Description of Technology: The invention is in the field of Photoimmunotherapy (PIT). More specifically, the invention relates to antibody-fluorophore conjugates where the antibody is specific for cancer cells and the fluorophore is IR700 dye. Binding of such conjugates to targeted cancer cells followed by irradiation with near infrared light (NIR) was shown to kill cancer cells in a highly specific manner. Furthermore, the invention discloses that the therapeutic effect of the PIT conjugate is significantly enhanced by the administration of one or more anti-cancer agents following the irradiation step. This is achieved by the markedly rapid accumulation of the therapeutic agent in the PIT-treated tissue. Also provided in the invention are wearable devices that incorporate NIR light emitting diodes (LEDs) and can be used to activate the PIT conjugates.

Potential Commercial Applications: Anti-cancer therapy.

Competitive Advantages:
- Highly specific to cancer cells
- Do not affect surrounding normal cells
- Negligible toxicity
- Enhancement of therapeutic effects when administered in combination with one or more other therapeutic agents
- Possible to follow the cell killing process in real time, using fluorescence lifetime imaging

Development Stage: In vivo data available (animal).

Inventors: Hisataka Kobayashi and Peter L. Choyke (NCI).

Publications:

1. Mitsunaga M, et al. Immediate in vivo target-specific cancer cell death after near infrared photoimmunotherapy. BMC Cancer 2012 Aug 8;12: 345. [PMID 22873679]
2. Mitsunaga M, et al. Near-infrared theranostic photoimmunotherapy (PIT): Repeated exposure of light enhances the effect of immunoconjugate. Bioconjug Chem. 2012 Mar 21;23(3):604–9. [PMID 22369484]
3. Mitsunaga M, et al. Cancer cell-selective in vivo near infrared photoimmunotherapy targeting specific membrane molecules. Nat Med. 2011 Nov6;17(12):1685–91. [PMID 22057348]

Intellectual Property:
- HHS Reference No. E–205–2010/2—PCT Application No. PCT/US2012/044421 filed 27 Jun 2012
- HHS Reference No. E–250–2010/1—U.S. Application No. 13/180,111 filed 11 Jul 2011
- HHS Reference No. E–205–2010/0—U.S. Provisional Application No. 61/636,079 filed 09 Jul 2010

Licensing Contact: Uri Reichman, Ph.D., MBA; 301–435–4616; *reichmau@mail.nih.gov.*

Dated: January 18, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–01620 Filed 1–25–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

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 meeting.

The meeting 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 property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity Applications.

Date: February 15, 2013.

Time: 10:00 p.m. to 11:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 18, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–01621 Filed 1–25–13; 8:45 am]

BILLING CODE 4140–01–P