

the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 22, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 19, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012-18095 Filed 7-24-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Risks and Benefits of Hydroxyethyl Starch Solutions; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: "Risks and Benefits of Hydroxyethyl Starch Solutions." The purpose of this public workshop is to discuss new information on the risks and benefits of FDA-approved hydroxyethyl starch (HES) solutions.

The public workshop has been planned in partnership with the Department of Defense and the National Heart, Lung and Blood Institute, National Institutes of Health, and will include presentations and panel

discussions with experts from academia, regulated industry, government, and other stakeholders.

Date and Time: The public workshop will be held on September 6, 2012, from 8:00 a.m. to 5:30 p.m., and September 7, 2012, from 8:30 a.m. to 1:00 p.m.

Location: The public workshop will be held at the Masur Auditorium, National Institutes of Health, 10 Center Dr., Bldg. 10, Clinical Center, Bethesda, MD 20892.

Contact Person: Jennifer Scharpf, Center for Biologics Evaluation and Research (HFM-300), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, Phone: 301-827-6128, FAX: 301-827-2843, email: CBEROBRRWorkshops@fda.hhs.gov.

Registration: Mail, fax, or email your registration information (including name, title, firm or organization name, address, telephone and fax numbers, and email address) to Jennifer Scharpf (see *Contact Person*) by August 15, 2012. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:00 a.m. If you need special accommodations due to a disability, please contact Jennifer Scharpf (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: HES solutions are synthetic colloids administered intravenously to patients to maintain or expand plasma volume when clinically indicated. Currently, three such products are approved by FDA. HES solutions are indicated for the treatment of hypovolemia (low blood volume) that may result from trauma, sepsis, burns, or anaphylaxis. These products are used in the prehospital and hospital environment in both military and civilian settings. This public workshop will serve as a forum for discussing new information on the potential effects of HES solutions on hemostasis and on the renal system.

The first day of the public workshop will include presentations and panel discussions on the following topics: (1) The risks and benefits associated with HES solutions in different clinical settings and (2) the findings of two recent major clinical studies conducted on HES solutions.

The second day of the public workshop will include a summary discussion and presentations concerning the overall safety profile of HES solutions and a discussion of future

clinical research for the evaluation of HES solutions.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: July 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-18110 Filed 7-24-12; 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.

Novel Analogues of the Asthma Drug Fenoterol as Liver and Brain Cancer Therapeutic Agents

Description of Technology: Available for licensing are specific fenoterol analogues, such as MNF, that inhibit the growth of various types of cancers, including brain, liver, colon, and lung tumors. MNF acts as an agonist of the

GPRSS cannabinoid (CB) receptor and, as such, represents one of the first potential drugs directed at this target. MNF crosses the blood brain barrier and initial toxicity studies indicate that it has few off-target effects. These new analogues can be used to treat CB receptor related disorders and diseases, and in particular GRPSS-related disorders and diseases, including brain and liver cancers for which there are no current effective treatments.

Potential Commercial Applications:

- A new class of compounds that can be used to treat cannabinoid receptor related disorders and diseases.

- Treatments for liver, brain, colon, and lung cancers.

Competitive Advantages:

- Able to cross the blood:brain barrier.
- Few side-effects.
- Broad range of therapeutic activity.
- Can be formulated for oral administration.

Development Stage:

- Pre-clinical.
- *In vitro* data available.
- *In vivo* data available (animal).

Inventors: Irving Wainer, Michel Bernier, Rajib Paul (all of NIA).

Publications:

1. Paul RK, *et al.* Cannabinoid receptor activation correlates with the pro-apoptotic action of the beta2-adrenergic agonist (R,R')-4'-methoxy-1-naphthylfenoterol. *J Pharmacol Exp Ther.*, in press.

2. Paul RK, *et al.* Negative regulation of GPR-55-mediated ligand uptake and cellular motility by (R,R')-4'-methoxy-1-naphthylfenoterol. *Br J Pharmacol.*, in preparation.

3. Paul RK, *et al.* The role of GPR55 and apoptotic signalling pathways in (R,R')-4'-methoxy-1-naphthylfenoterol. *Cancer Res.*, in preparation.

Intellectual Property: HHS Reference No. E-139-2012/0—U.S. Provisional Application No. 61/651,961 filed 25 May 2012.

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

Collaborative Research Opportunities: The IRP/NIA/LCI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize (R,R')-4'-methoxy-1-naphthylfenoterol for the treatment of brain, liver and colon carcinomas. For collaboration opportunities, please contact Nicole Guyton, Ph.D. at darackn@mail.nih.gov.

High-Affinity Mouse Monoclonal Antibodies to Glypican-3 (GPC3) for Research Use

Description of Technology: Liver cancer is the fifth most common cancer in the world, with hepatocellular cancer (HCC) representing the preponderance of these liver cancers. As with many cancers, positive prognosis for a patient diagnosed with HCC correlates with the early detection of the disease. Unfortunately, HCC is usually detected at a late stage in its development, leading to poor prognosis for most patients. As a result, there is great interest and value in developing new agents which can detect the presence of HCC in a patient at an early stage.

Glypican-3 (GPC3) is a cell surface heparan sulfate glycoprotein that is expressed on the vast majority of HCC cells. The correlation between GPC3 expression and HCC makes GPC3 an attractive candidate for studying the disease progression and treatment of HCC. The presence, progression and treatment of this disease can potentially be monitored by tracking the level of expression of GPC3 on cells. This can be accomplished using monoclonal antibodies which recognize only GPC3, particularly the cell surface domain of the protein. This invention concerns the generation of several monoclonal antibodies that are specific for the cell surface domain of GPC3 (YP6, YP7, YP8, YP9 and YP9.1), and which can be used as research reagents for studying the role of GPC3 in HCC.

Potential Commercial Applications: Antibodies for use as research materials, including:

- Detection of cells that express GPC3 for monitoring HCC disease progression and treatment.
- Immunostaining for tumor imaging.
- ELISA and immunohistochemistry applications.

- Any other antibody-related research use, including immunoprecipitation, western blot analysis, etc.

Competitive Advantages:

- Higher binding affinity (subnanomolar levels) than commercially available GPC3 antibodies such as 1G12.

- Recognition of cells with low levels of GPC3 expression.

- Able to bind to wild-type GPC3 (conjugated to heparan sulfate) better than the GPC3 core protein (lacking heparan sulfate).

Development Stage:

- Early-stage.
- *In vitro* data available.

Inventors: Mitchell Ho et al. (NCI).

Publications:

1. Ho M, Kim H. Glypican-3: a new target for cancer immunotherapy. *Eur J*

Cancer. 2011 Feb; 47(3):333-338. [PMID 21112773]

2. Ho M. Advances in liver cancer antibody therapies: a focus on glypican-3 and mesothelin. *BioDrugs.* 2011 Oct 1; 25(5):275-284. [PMID 21942912]

Intellectual Property: HHS Reference No. E-136-2012/0—U.S. Provisional Application No. 61/654,232 filed 01 Jun 2012.

Related Technology: HHS Reference No. E-130-2011/0 — U.S. Provisional Application No. 61/477,020 filed 19 Apr 2011; PCT Application No. PCT/US2012/034186 filed 19 Apr 2012.

Licensing Contact: David A.

Lambertson, Ph.D.; 301-435-4632; lambertsond@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 cancer diagnostics, isolation of circulating tumor cells, humanization and/or immunoconjugates. For collaboration opportunities, please contact John Hewes, Ph.D. at hewesj@mail.nih.gov.

Self-Assembled Ferritin Nanoparticles Expressing Hemagglutinin as an Influenza Vaccine

Description of Technology: NIH inventors at the Vaccine Research Center have developed a novel influenza virus hemagglutinin (HA)-ferritin nanoparticle influenza vaccine that is easily manufactured, potent, and elicits broadly neutralizing influenza antibodies against multiple strains of influenza. This novel influenza nanoparticle vaccine elicited two types of broadly neutralizing, cross-protective antibodies, one directed to the highly conserved HA stem and a second proximal to the conserved receptor binding site (RBS) of the viral HA, providing a new platform for universal and seasonal influenza. In addition, HA-ferritin nanoparticles can be easily produced from simple expression vectors and without the production of infectious virus in eggs, and will facilitate influenza preparedness in the face of emerging epidemics.

This technology exploits ferritin, a ubiquitous iron storage protein, that self-assembles into spherical nanoparticles and could serve as a scaffold to express a heterologous protein, such as influenza HA, so it mimics a physiologically relevant trimeric viral spike. Immunization with the HA-ferritin nanoparticle elicited neutralizing antibody titers that were >10-fold higher than a matched inactivated vaccine. The immune sera raised by HA-ferritin nanoparticles

expressing a 1999 HA neutralized seasonal H1N1 viruses from 1934 to 2007 and protected ferrets from an unmatched 2007 H1N1 virus challenge. This extended neutralization coverage is partially explained by the presence of both type of antibodies, antibodies directed to the conserved HA stem and against the RBS region. Finally, this ferritin nanoparticle vaccine platform has significant advantages in the ability to utilize specific multimerized spikes and it may be applicable to other viral proteins.

Potential Commercial Applications: The ferritin nanoparticles as a vaccine platform can be used to deliver vaccines, such as influenza vaccines, with enhanced magnitude and breadth of the neutralizing antibody responses. This vaccine platform may be applicable to other viral proteins.

Competitive Advantages:

- Forms an octahedron consisting of 24 subunits, allowing for greatly increased presentation of heterologous protein on the ferritin nanoparticles surface, compared to other vaccine platforms.

- *In vivo* data in multiple animal models demonstrated induction of broader and more potent antibody responses.

- Vaccine stimulated broadly neutralizing antibodies against the highly conserved epitope on the HA stem region and against the RBS, thus targeting two independent sites of vulnerability on HA.

- Multivalent influenza HA ferritin vaccines have been tested in animal models.

- Ferritin is extremely stable to temperature ranges, pH, detergent and other factors.

- Easily manufactured, will facilitate influenza preparedness in the face of emerging epidemics.

Development Status:

- Preclinical.

- *In vitro* data available.

- *In vivo* data available (animal).

Inventors: Gary Nabel, Masaru Kanekiyo, Jeffrey C. Boyington, Patrick McTamney (all of NIAID).

Publication: Kanekiyo M, et al. A Self-Assembling Influenza Nanoparticle Vaccine Elicits Two Types of Broadly Neutralizing and Cross-protective Antibodies. Manuscript submitted.

Intellectual Property:

- HHS Reference No. E-293-2011/0 — U.S. Provisional Application No. 61/538,663 filed 23 Sep 2011.

- HHS Reference No. E-293-2011/1 — U.S. Provisional Application No. 61/661,209 filed 18 Jun 2012.

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., M.B.A.;

301-435-4507;
ThalhamC@mail.nih.gov.

Salen-Manganese Compounds for Therapy of Viral Infections

Description of Technology: Salen-manganese compounds are synthetic, stable, low toxicity, low cost agents that may provide protection from immune reaction-related oxidative cell damage associated with many illnesses. In particular, oxidative cell damage has been associated with many viral infections including influenza. This invention demonstrates that treating mice with salen-manganese compounds, after lethal pandemic influenza virus infection, significantly enhances survival. Salen-manganese treatment also reduces lung pathology and also improved cellular recovery and repair. Because oxidative damage is observed in many viral infections, administration of salen-manganese compounds may have therapeutic relevance to a wide range of viral infections, in addition to influenza. Existing viral therapeutics merely target the infectious viral agent and not the damage caused by the immune system reaction related to infection. Because, salen-manganese treatments target the untapped therapeutic space of infection-induced, immune system-related pathology and have favorable safety and cost profiles, such therapies are ideal candidates for development.

Potential Commercial Applications: Viral therapeutics.

Competitive Advantages: Synthetic, stable, low toxicity, low cost, untapped therapeutic target space.

Development Stage:

- Early-stage.

- Pre-clinical.

- *In vivo* data available (animal).

Inventors: John Kash (NIAID), Jeffrey Taubenberger (NIAID), Rodney Levine (NHLBI), Susan Doctrow (Boston University).

Publications:

1. Doctrow SR, et al. Salen Manganese Complexes: Multifunctional Catalytic Antioxidants Protective in Models for Neurodegenerative Diseases of Aging. In: Medicinal Inorganic Chemistry, ACS Symposium Series, Vol. 903, Chapter 18, pp 319-347; August 25, 2005. [DOI: 10.1021/bk-2005-0903.ch018.]

2. Schwarz KB. Oxidative stress during viral infection: a review. Free Radic Biol Med. 1996; 21(5):641-9. [PMID 8891667]

Intellectual Property: HHS Reference No. E-281-2011/0—U.S. Provisional Application No. 61/558,137 filed 10 Nov 2011.

Licensing Contact: Tedd Fenn, J.D.; 301-435-5031; Tedd.Fenn@nih.gov.

Collaborative Research Opportunity: The NIAID Laboratory of Infectious Diseases, Viral Pathogenesis and Evolution Section, 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 at 301-594-6656.

Dated: July 18, 2012.

Richard U. Rodriguez,

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

[FR Doc. 2012-18054 Filed 7-24-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date: September 25, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2081, Rockville, MD 20852, 301-443-0800, bbuzas@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research