Advisory Committee. This meeting was announced in the **Federal Register** of November 17, 2011 (76 FR 71349). The amendment is being made to reflect a change in the *Date and Time, Agenda,* and *Procedure* portions of the document. We are cancelling (Topic 1), the portion of the meeting relating to the appropriate types of clinical evidence for developing anti-inflammatory drugs for the treatment of postoperative inflammation and reduction of ocular (eye) pain in patients who have undergone ocular surgery. The portion of the meeting (Topic 2), relating to the appropriateness of marketing a single bottle of anti-inflammatory ophthalmic products for use in both eyes for post-surgical indications as it relates to the potential risk for infection will still be held on the same date (February 27, 2012), the time for the meeting has been changed to 9 a.m. to 3 p.m.

FOR FURTHER INFORMATION CONTACT: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. WO31–2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *DODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301 443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 17, 2011, FDA announced that a meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee would be held on February 27, 2012. On page 71349, in the first column, the *Date and Time* portion of the document is changed to read as follows:

Date and Time: The meeting will be held on February 27, 2012, from 9 a.m. to 3 p.m.

On page 71349, in the second column, the *Agenda* portion of the document is changed to read as follows:

Agenda: The committee will be asked to comment on the appropriateness of marketing a single bottle of anti-inflammatory ophthalmic products for use in both eyes for post-surgical indications as it relates to the potential risk for infection. The FDA's Center for Drug Evaluation and Research would like the advisory committee to provide advice on the potential risk and approaches to mitigating that risk, including limits to fill size where appropriate.

On page 71349, in the third column, the third sentence in the Procedure portion of the document is changed to read as follows:

Procedure: Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 8, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–3343 Filed 2–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Anti-mesothelin Targeted Immunotoxins for the Treatment of Cancer

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in US Patent application 61/535,668 entitled ''Pseudomonas Exotoxin A with Less Immunogenic B Cell Epitopes'' [HHS Ref. E–263–2011/0–US–01], US Patent application 61/495,085 entitled ''Pseudomonas Exotoxin A with Less Immunogenic T Cell Epitopes'' [HHS Ref. E–174–2011/0–US–01], US Patent application 61/483,531 entitled ''Recombinant Immunotoxin Targeting Mesothelin'' [HHS Ref. E–117–2011/0–US–01], U.S. Patent Application 61/241,620 entitled ''Development of an Immunotoxin in Which All B–Cell Epitopes Have Been Removed and Which Has High Cytotoxic Activity'' [HHS Ref. E–269–2009/0–US–01], U.S. Patent Application 60/969,929 entitled ''Deletions in Domain II of Pseudomonas Exotoxin A That Reduce Non-Specific Toxicity'' [HHS Ref. E–292–2007/0–US–01], U.S. Patent Application 60/703,798 entitled ''Mutated Pseudomonas Exotoxins with Reduced Antigenicity'' [HHS Ref. E–262–2005/0–US–01], U.S. Patent Application 60/160,071 entitled ''Immunoconjugates Having High Binding Affinity'' [HHS Ref. E–139–1999/0–US–01], U.S. Patent Application 60/067,175 entitled ''Antibodies, Including Fv Molecules, and Immunoconjugates Having High Binding Affinity for Mesothelin and Methods for Their Use'' [HHS Ref. E–021–1998/0–US–01], U.S. Patent Application 60/010,166 entitled ''Molecular Cloning of Mesothelin, a Differentiation Antigen Present on Mesothelium, Mesotheliomas and Ovarian Cancers'' [HHS Ref. E–002–1996/0–US–01], PCT Application PCT/US97/00224 entitled ''Mesothelin Antigen and Methods and Kits for Targeting It'' [HHS Ref. E–002–1996/1–PCT–01], U.S. Patent 5,747,654 entitled ''Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity'' [HHS Ref. E–163–1993/0–US–01], PCT application PCT/US96/16327 entitled ''Immunotoxin Containing A Disulfide-Stabilized Antibody Fragment'' [HHS Ref. E–163–1993/2–PCT–01], and all continuing applications and foreign counterparts, to Hoffman-La Roche, Inc. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to:

The use of anti-mesothelin targeted immunotoxins for the treatment of mesothelin-expressing cancers, wherein the immunotoxins have: (1) A targeting domain containing the complementary determining regions (CDR) of the SS1 antibody and (2) a *Pseudomonas* exotoxin A (''PE'') toxin domain that is (a) lysosomal protease resistant (PE–LR) and (b) lacks at least one major B-cell epitope due to the alteration of an amino acid. The immunotoxin may include additional alterations to B-cell and T-cell epitopes for reduction of immunogenicity, as well as a peptide linker sequence.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before March 15, 2012 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, PhD, Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4632; Facsimile: (301) 402–0220; Email: *lambertsond@od.nih.gov.*

SUPPLEMENTARY INFORMATION: These inventions concern immunotoxins which are targeted to mesothelin-expressing cancer cells, and methods of

using the immunotoxins for the treatment of mesothelin-expressing cancers (such as mesothelioma, ovarian cancer and pancreatic cancer). The specific immunotoxin will have an antibody targeting domain that contains the CDRs of the antibody identified as SS1, which was invented at the NIH. The specific immunotoxin will also have a toxin domain derived from PE that is resistant to lysosomal proteases due to the deletion of a large portion of the exotoxin, and which lacks at least one major B-cell epitope due to the alteration an amino acid. Ultimately, the PE used in the immunotoxin may lack multiple B-cell epitopes, as well as multiple T-cell epitopes, in an effort to minimize immunogenicity.

Alterations to the toxin that reduce immunogenicity improve the therapeutic value of the immunotoxin while maintaining its ability to trigger cell death. Since mesothelin is preferentially expressed on certain types of cancer cells, the immunotoxins selectively bind and kill only those cancer cells, allowing healthy, essential cells to remain unharmed. This results in an effective therapeutic strategy with fewer side effects.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7 within thirty (30) days from the date of this published notice.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February 8, 2012.

Richard U. Rodriguez,

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

[FR Doc. 2012–3410 Filed 2–13–12; 8:45 am]

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, 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.

ADDRESSES: 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.

Encapsulated N–Acetylmannosamine or N–Acetylneuraminic Acid as a Therapeutic Agent for Increasing Sialylation in Certain Muscular Atrophies, Kidney Disorders, Cancers or Poor Immune Function

Description of Technology: N-acetylmannosamine is a precursor for the synthesis of sugar molecules known as sialic acids, which play an important role in specific biological processes such as cellular adhesion, cellular communication and signal transduction. Lack of sialic acids also plays a crucial role in disease processes such as inflammation, immune responses, as well as certain muscular atrophies (including hereditary inclusion body myopathy (HIBM) and distal myopathy with rimmed vacuoles (DMRV or Nonaka myopathy)), certain kidney disorders with proteinuria and hematuria (including minimal change nephrosis and focal segmental glomerulosclerosis), and certain cancers (including bladder cancer and myeloid leukemia).

This technology relates to methods of administering liposome-encapsulated N-acetylmannosamine, N-acetylneuraminic acid, or their derivatives to treat human disorders of hyposialylation (by increasing sialic acid production in patients who are deficient in that sugar molecule). Liposome-encapsulated delivery of these monosaccharides enhances successful systemic delivery, including to the central nervous system (crossing the blood-brain barrier), and liposome encapsulation protects against gastrointestinal tract degradation.

Potential Commercial Applications:

- Treatment of rare diseases such as HIBM and Nonaka myopathy (or DMRV).
- Treatment of kidney conditions involving sialic acid deficiencies, resulting in proteinuria and hematuria.
- Treatment of other diseases involving sialic acid deficiencies.
- Use as immune stimulant since adequate sialic acid is important for robust immune function.

Competitive Advantages:

- N-acetylmannosamine is the only uncharged sugar in the sialic acid biosynthesis pathway (thus making it easier to deliver than charged sugars) and is located after the rate-limiting step.
- N-acetyl mannosamine and N-acetylneuraminic acid have been shown to rescue hyposialylation in mouse models of HIBM.
- Encapsulated N-acetylmannosamine or N-acetylneuraminic acid crosses the blood-brain barrier and prevents gastrointestinal tract degradation more efficiently than unencapsulated drug.

Development Stage:

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

Inventors: Marjan Huizing et al. (NHGRI).

Publications:

1. Galeano B, *et al.* Mutation in the key enzyme of sialic acid biosynthesis causes severe glomerular proteinuria and is rescued by N-acetylmannosamine. J Clin Invest. 2007 Jun;117(6):1585–1594. [PMID 17549255]

2. Nemunaitis G, *et al.* Hereditary inclusion body myopathy: single patient response to intravenous dosing of GNE gene lipoplex. Hum Gene Ther. 2011 Nov;22(11):1331–1341. [PMID 21517694]

3. Kakani S, *et al.* The Gne M712T mouse as a model for human glomerulopathy. Am J Pathol., in press (Dec 2011) (available online in Feb 2012)

Intellectual Property: HHS Reference No. E–270–2011/0 — U.S. Application No. 61/531,934 filed 07 Sep 2011.

Licensing Contact: Tara L. Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov.*