of all the information presented, the open session of the meeting will close so the SAB members can discuss personnel issues at NCTR at the end of the day.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: On December 3, 2019, from 8 a.m. to 5:55 p.m., and December 4, 2019, from 8 a.m. to 11:30 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 26, 2019. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on December 3, 2019. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 18, 2019. Time allotted for each presentation may be limited. If 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 November 19, 2019.

Closed Committee Deliberations: On December 4, 2019, from 11:30 a.m. to 12:00 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

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 disabilities. If you require accommodations due to a disability, please contact Donna Mendrick at least 14 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://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: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23413 Filed 10–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of an Anti-GPC3 Radionuclide Immunoconjugate for the Treatment of GPC3-Expressing Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of 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 the Patents and Patent Applications listed in the Supplementary Information section of this notice to Xsto BioSciences, Inc. (Xsto), located in San Carlos, California.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before November 12, 2019 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702 Telephone: (240)–276–5530; Facsimile: (240)–276–5504 Email: *david.lambertson@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application 61/477,020 entitled ''Human Monoclonal Antibody Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–US–01], PCT Patent Application PCT/US2012/034186 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–PCT–02], Chinese Patent 201280029201.3 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–CN–03], European Patent 2699603 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–EP–04], and validated in France [HHS Ref. E–130–2011–0–FR–09], Germany [HHS Ref. E–130–2011–0–DE–08] and the United Kingdom [HHS Ref. E–130–2011–0–GB–10] and lodged in Hong Kong [HHS Ref. E–130–2011–0–HK–11], United States Patent 9,206,257 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–US–05], United States Patent 9,394,364, entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–US–06], European Patent 2998320 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–EP–07], and validated in France [HHS Ref. E–130–2011–0–FR–23], Germany [HHS Ref. E–130–2011–0–DE–22] and the United Kingdom [HHS Ref. E–130–2011–0–GB–24], United States Patent 9,932,406 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–US–12], Chinese Patent Application 201610290837.3 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–CN–13], European Patent 3070104 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof'' [HHS Ref. E–130–2011–0–EP–14], and validated in France [HHS Ref. E–130–2011–0–FR–18], Germany [HHS Ref. E–130–2011–0–DE–16], the United Kingdom [HHS Ref. E–130–2011–0–GB–19], Italy [HHS Ref. E–130–2011–0–IT–20] and Spain [HHS Ref. E–130–2011–0–ES–17] and lodged in Hong Kong [HHS Ref. E–130–2011–0–HK–15], United States Patent Application 15/843,256 entitled ''Human Monoclonal Antibodies Specific for Glypican-3 And Use

Thereof'' [HHS Ref. E–130–2011–0–US–21], and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned 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

(I) The development and commercialization of glypican-3 (GPC3) antibody-based radionuclide conjugates comprising of at least:

a. The complementary determining region (CDR) sequences of the anti-GPC3 antibody known as HN3, and

b. A radionuclide, including but not limited to an alpha, beta, positron, gamma or auger emitting radionuclide, for the treatment of GPC3-expressing cancers.

(II) The development of an FDA-approved *in vivo* radiopharmaceutical, using a binder having the CDR sequences of the anti-GPC3 antibody known as HN3, for the diagnosis and monitoring of GPC3-expressing cancers.

The licensed field of use excludes any (a) non-specified immunoconjugates, including, but not limited to, chimeric antigen receptors (CARs) and variants thereof, immunotoxins, and antibody drug conjugates, and (b) unconjugated antibodies.

This technology discloses monoclonal antibodies that are specific for the cell surface domain of GPC3. These antibodies can potentially be used for the treatment of GPC3-expressing cancers such as HCC. In the subject situation, the antibodies can be used in conjunction to target a radionuclide specifically to GPC3-expressing cells, leading to the selective destruction of the cancerous cells.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute 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.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: October 23, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019–23481 Filed 10–25–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Center for Complementary and Integrative Health Special Emphasis Panel; Exploratory Clinical Trials of Mind and Body Interventions (MB).

Date: December 3, 2019.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Martina Schmidt, Ph.D., Chief Office of Scientific Review, National Center for Complementary & Integrative Health, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301–594–3456, *schmidma@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: October 22, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23402 Filed 10–25–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Center for Complementary and Integrative Health Special Emphasis Panel Exploratory Clinical Trials of Mind and Body Interventions (MB).

Date: December 3, 2019.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pamela Jeter, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH, NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892–547, 301–435–2591, *pamela.jeter@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: October 22, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23400 Filed 10–25–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings. The meetings 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.,