DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Risk Communications Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communications Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 17, 2013, from 9 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Luis G. Bravo, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3274, 240–402–5274, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

If you are unable to join us in person, we encourage you to watch the free Webcast. Visit the Risk Communication Advisory Committee Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/default.htm.* The link will become active shortly before the open session begins at 9 a.m.

Agenda: On December 17, 2013, the Committee will meet to identify and discuss new methods for communicating risk information as part of Risk Evaluation and Mitigation Strategies (REMS) to health care providers. The discussion will also address how sponsors and FDA can evaluate whether REMS communications are reaching the targeted population, are increasing awareness and understanding of the key risk messages, as well as whether the communications are having the intended impact on knowledge, behaviors, and/or outcomes.

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 Web site 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 Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: 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 December 10, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 December 2, 2013. 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 December 3, 2013.

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 Luis G. Bravo 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: November 21, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–28435 Filed 11–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1424]

Transport Format for the Submission of Regulatory Study Data; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in the Food and Drug Administration (FDA) are announcing a pilot project to evaluate the Clinical Data Interchange Standard Consortium (CDISC) Submission Data Standards (SDS) Extensible Markup Language (XML) transport format for the submission of regulatory study data. The current study data transport format supported by FDA is the SAS Transport (XPORT) version 5 file format. Although XPORT has been a reliable exchange format for many years, it is not an extensible modern technology. SDS XML is an extension of the CDISC Operational Data Model, which is a vendor neutral, platform-independent format for the exchange and archive of study data. FDA is announcing an invitation to sponsors to participate in this pilot project to evaluate the SDS XML transport format.

DATES: Submit either electric or written requests for participation in the pilot project by January 27, 2014.

ADDRESSES: Submit electronic requests to participate in the pilot and comments regarding this pilot project to *http://www.regulations.gov.* Summit written requests and comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1062, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1160, Silver Spring, MD 20993, 301–796–5333, *ronald.fitzmartin@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the 1999 ''Guidance to Industry: Providing Regulatory Submissions in Electronic Format'' FDA recommended that regulatory submissions of clinical data to FDA utilize SAS Institute's open transport called XPORT version 5 format (XPORT). The XPORT format was developed in the late 1980s and there have been no version updates since 1999. XPORT is now considered by many to be an outdated transport technology for transferring data across different hardware and operating systems.

Following a **Federal Register** Notice, FDA held a public meeting on November 5, 2012, entitled ''Regulatory New Drug Review: Solutions for Study Data Exchange Standards.'' The purpose of the public meeting was to solicit input from industry, technology vendors, and other members of the public regarding the advantages and disadvantages of current and emerging open, consensus-based standards for the exchange of regulated study data. FDA indicated, in the Notice and at the meeting, based on feedback received at the public meeting and other information sources, it would undertake further requirements analysis in support of expected evaluation projects.

II. Project Participation

FDA envisions several pilot projects conducted to evaluate new transport formats. The purpose of this pilot project is to obtain additional experience with CDISC SDS XML format. A successful pilot may allow CDER and CBER to routinely receive study data that employ CDISC SDS XML format as the transport format once an alternatives analysis is completed. As part of this pilot, FDA would like to have sponsors participate in the preparation and submission of previously submitted study datasets using the SDS XML transport format. Participation in this evaluation will be outside of the regulatory pathway and, as such, will not be used to make regulatory decisions.

FDA expects that the pilot will assess the technical capability of SDS XML to exchange and archive regulatory study data in investigational new drug applications, new drug applications, and biologics licensing applications.

III. Requests for Participation

Requests to participate in the SDS XML pilot project are to be identified with the docket number found in brackets in the heading of this document. Interested persons should include the following information in the request: Contact name, contact phone number, email address, name of the sponsor, address, and license number. Once requests for participation are received, FDA will contact interested sponsors to discuss the pilot project. FDA is seeking a limited number of sponsors (approximately three to five, but no more than six) to participate in this project. The elapsed time duration of the pilot is expected to be approximately 12 months but may be extended as needed. Participants should be willing to provide previously submitted study data using both the SAS XPORT version 5 format and the CDISC SDS XML format.

Dated: November 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28391 Filed 11–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: GMCSF-BclxL-Derived Chimeric Therapeutics for Use in Treatment of Cancer, Neutropenia, CNS Injury and Parkinson's Disease

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, indicates 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 technology family E–150–2005/0, including U.S. Patent application 11/991,692 [HHS Ref. E–150–2005/0–US–07], PCT Application PCT/US06/35070 [HHS Ref. E–150–2005/0–PCT–02] and foreign equivalents thereof, entitled ''Methods and Compositions for Inhibiting Cell Death or Enhancing Cell Proliferation'', to Medicenna Therapeutics, Inc., located in Vancouver, Canada. 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 patent license territory may be worldwide, and the field of use may be limited to:

Development and commercialization of GMCSF-BclxL-derived chimeric therapeutics and immunotherapeutics, alone or in combination, for restoring, protecting, or stimulating cells in order to treat (i) cancer, (ii) neutropenia, (iii) CNS injury and (iv) Parkinson's disease.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before December 27, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive patent license should be directed to: Surekha Vathyam, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4076; Facsimile: (301) 402–0220; Email: *vathyams@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The subject invention is to a chimeric protein comprising human granulocyte-macrophage colony stimulating factor (GMCSF) and B-cell lymphoma-extra large (BclxL). Chimeric proteins such as GMCSF-BclxL and its analogs have the potential to enhance cell survival, inhibit apoptosis and promote cell growth or proliferation (collectively referred to as ''anti-apoptotic''). Such anti-apoptotic proteins could have utility for restoring, protecting and stimulating cells in patients to treat a variety of disorders.

This technology relates to compositions comprising an anti-apoptotic chimeric protein and its use to inhibit apoptosis *in vivo* and *ex vivo.* One domain of the chimeric protein is the ligand for GMCSF receptor. Receptors for GMCSF are found on a