of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastrointestinal Drugs 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 January 12, 2011, from 8 a.m to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, Bldg. 31, the Great Room, White Oak Conference Center (rm. 1503). 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 "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings." Please note that visitors to the White Oak Campus must have a valid driver's license or other picture ID, and must enter through Building 1.

Contact Person: Kristine T. Khuc, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, *FAX:* 301–847–8533, *e-mail: kristine.khuc@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512538. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On January 12, 2011, the committee will discuss the safety and efficacy of new drug application (NDA) 022–486, for Solpura (liprotamase) Capsules, by Alnara Pharmaceuticals, for the proposed indication (use) in the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy (surgical removal of all or part of the pancreas), or other conditions that may impair or limit function of the pancreas. The pancreas is an organ involved, in part, in the digestion of food through the use of specialized proteins called enzymes. Exocrine pancreatic insufficiency is a decreased ability to digest food due to deficient enzyme production by the pancreas.

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 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 28, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. to 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 17, 2010. 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 20, 2010.

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 Kristine T. Khuc 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 26, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30274 Filed 12–1–10; 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.

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.

Novel Compositions and Methods To Treat Glioblastoma and Other Cancers

Description of Technology: There remains a significant unmet need for therapeutics to treating glioblastoma multiforme, a very aggressive type of brain tumor. Glioblastoma is difficult to treat with conventional surgery, chemical, and radiation therapies. With approximately 18,000 new glioblastoma cases in the U.S. each year, and a comparable market in Europe, the global market for such products forecast to be over $300 million. In light of the high unmet need in malignant astrocytoma and little in the way of pipeline competition, this indication represents a potential easy route to market for new drugs.

Researchers at the National Cancer Institute (NCI) have identified two novel molecular targets, annexin 1 (Anx A1) and its receptor formyl peptide receptor 1 (FPR1), for new anti-glioblastoma therapies. Anx A1 and FPR1 mediate growth, invasion, production of angiogenic factors, tumor formation, and are abnormally expressed by more highly malignant glioblastomas. Depletion of Anx A1 in glioblastoma cells resulted in their reduced capacity to form tumors; additional depletion of FPR1 further reduced this capacity. Further, the NCI researchers have found a correlation between Anx A1 expression and the degree of malignancy of human gliomas.

Novel anti-glioblastoma therapies encompassed by this invention include neutralizing antibodies against Anx A1 and FPR1, small compound agonists of Anx A1 and FPR1, small interference RNAs (siRNAs) that deplete Anx A1 and FPR1 from glioblastoma cells, as well as delivery methods to effectively administer the Anx A1 and FPR1 targeting drugs into brain tissues.

Applications

- Treatment of glioblastoma multiforme and other brain tumors.
- Treatments for inhibiting neoplastic cell growth.
- Treatments for inhibiting tumor progression and metastasis.
- Treatments for inhibiting angiogenesis in a tumor.

Advantages

- High specificity.
- Does not require radiation.
- A correlation between expression of the molecular target and the degree of tumor malignancy is known.
- Wide-range/flexibility of potential therapies and approaches.

Development Status: Pre-clinical.

Inventors: Ji Ming Wang *et al.* (NCI).

Relevant Publication: Y Zhou, *et al.* Formylpeptide receptor FPR and the rapid growth of malignant human gliomas. J Natl Cancer Inst. 2005 Jun 1;97(11):823–835. [PubMed: 15928303]

Patent Status: U.S. Provisional Application No. 61/388,983, filed 01 Oct 2010 (HHS Reference No. E–297–2010/0–US–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Molecular Immunoregulation, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Synovial Sarcoma X Breakpoint-2 (SSX–2) Specific Human T Cell Receptors for Treating a Wide-Range of Cancers

Description of Technology: Many current approaches for treating cancer also generate harsh side effects in patients. In addition, a sizable patient population does not respond to generalized chemotherapy and radiation treatments for cancer. There is an urgent need to develop new therapeutic strategies aimed at reducing side-effects and increasing specific anti-tumor activity in individual patients. Adoptive immunotherapy is a promising new approach to cancer treatment that engineers an individual's innate and adaptive immune system to fight against specific diseases, including cancer. As research and development continues in this area, scientists continue to improve cell transfer therapies by targeting an increasing collection of tumor antigens with more effective immune cell cultures.

T cell receptors (TCRs) are proteins that recognize antigens in the context of infected or transformed cells and activate T cells to mediate an immune response and destroy abnormal cells. TCRs consist of two domains, one variable domain that recognizes the antigen and one constant region that helps the TCR anchor to the membrane and transmit recognition signals by interacting with other proteins. When a TCR is stimulated by an antigen, such as a tumor antigen, some signaling pathways activated in the cell lead to the production of cytokines, which mediate the immune response.

Scientists at the National Institutes of Health (NIH) have developed T cells genetically engineered to recognize synovial sarcoma X breakpoint-2 (SSX–2) peptide antigens. SSX proteins, including SSX–2, are expressed primarily by tumor cells from a variety of cancers, including pancreatic cancer where very few treatment options exist. Other than germ cells of the testis, normal cells do not express SSX proteins and, thus, should not be targeted by therapies directed against these proteins. Therefore, SSX proteins represent a promising target for cancer immunotherapy. There are ten (10) known members of the SSX protein family designated SSX–1 through SSX–10. The T cell receptors (TCRs) developed by these NIH scientists have specificity for SSX–2 and deliver a robust immune response when they encounter SSX–2 expressing cells. However, these TCRs also recognize five (5) other SSX family members, including SSX–3, SSX–4, SSX–5, SSX–9, and/or SSX–10, and deliver a productive, intermediate immune response in the context of target cells expressing these antigens. This versatile antigen coverage could allow these SSX-specific TCRs to be utilized in the treatment of multiple types of cancer in a wide array of cancer patients. Infusing cancer patients with SSX–2 specific T cells via adoptive immunotherapy could prove to be a powerful approach for selectively attacking tumors without generating toxicity against noncancerous cells.

Applications

- Immunotherapeutics to treat and/or prevent the recurrence of a variety of human cancers, including pancreatic cancer and melanoma, by adoptively transferring the gene-modified T cells into patients whose tumors express a SSX family member protein recognized by this TCR.
- A drug component of a combination immunotherapy regimen aimed at targeting specific tumor-associated antigens, including SSX–2, SSX–3, SSX–4, SSX–5, SSX–9, and/or SSX–10 expressed by cancer cells within individual patients.
- A research tool to investigate signaling pathways in SSX–2 expressing cancer cells.
- An *in vitro* diagnostic tool to screen for cells expressing an SSX antigen from a recognized member of the SSX protein family.

Advantages

- *Selective toxicity for tumor cells*—SSX–2 and other SSX proteins are only expressed on testis germ cells and tumor cells. Thus, infused cells expressing an anti-SSX–2 TCR should target SSX-expressing tumor cells with little or no toxicity to normal cells. Immunotherapy with these cells is not anticipated to elicit harsh side effects to patients.
- *Ability to recognize multiple SSX antigens*—Since these SSX–2 directed TCRs can also recognize five (5) additional SSX family members (SSX–3, 4, 5, 9, and 10), cells expressing these TCRs are expected to be able to fight a larger range of tumor types. If in the course of attacking SSX–2 expressing tumor cells in a patient these cells also encounter tumor cells expressing other recognized SSX antigens, then these cells would still be capable of eliminating the non-SSX–2 expressing cell. The ability of these TCRs to recognize multiple SSX antigens may

allow it to be utilized to treat a broader population of patients.

• *Versatile antigen recognition*—These TCRs are CD8 and CD4 independent meaning that cells expressing these TCRs are capable of eliciting an immune response in the absence of CD8 or CD4 molecule expression on the T cell. When utilized for immunotherapy, this versatility allows engineered T cells expressing this TCR to recognize and eliminate tumors expressing SSX–2 regardless of how the antigen is presented to the T cell.

Development Status: This technology is in a preclinical stage of development.

Inventors: Richard A. Morgan *et al.* (NCI).

Publications

1. N Chinnasamy, *et al.* Development of HLA–A2 Restricted TCR Against Cancer Testis Antigen SSX–2 for Adoptive Immunotherapy of Cancer. Abstracts for the 25th Annual Meeting of the International Society for Biological Therapy of Cancer, J Immunother. 2010 Oct;33(8):860, DOI 10.1097/CJI.0b013e3181f1e08d.

2. D Valmori, *et al.* Expression of synovial sarcoma X (SSX) antigens in epithelial ovarian cancer and identification of SSX–4 epitopes recognized by CD4+ T cells. Clin Cancer Res. 2006 Jan 15;12(2):398–404. [PubMed: 16428478]

3. G Bricard, *et al.* Naturally acquired MAGE–A10- and SSX–2-specific CD8+ T cell responses in patients with hepatocellular carcinoma. J Immunol. 2005 Feb 1;174(3):1709–1716. [PubMed: 15661935]

Patent Status: U.S. Provisional Application No. 61/384,931 filed 21 Sept 2010 (HHS Reference No. E–269–2010/0–US–01).

Related Technologies: T cell receptor technologies developed against other CTAs: E–304–2006/0 and E–312–2007/1 (anti-NY–ESO–1) and E–236–2010/0 (anti-MAGE–A3).

Licensing Status: Available for licensing.

Licensing Contact: Samuel E. Bish, Ph.D.; 301–435–5282; bishse@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of T cell receptor gene therapy for the treatment of cancer. Please contact John Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 24, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–30279 Filed 12–1–10; 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.

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Mouse Monoclonal Antibody for CEACAM

Abstract: The following biological material is a hybridoma cell line generated from mice lymphocytes immunized with human mammary carcinomas and fused to a myeloma cell line. The resulting mouse monoclonal antibody (MAb, clone B1.1) is directed against carcinoembryonic antigen (CEA). CEA are glyco-proteins whose expression levels are increased on the surface of metastatic cancer cells. Therefore, antibodies generated from the hybridoma clone B1.1 can be used to detect cancer cells. MAb B1.1 binds to the surface of human breast and melanoma cell lines and cells associated with colon carcinomas and adenomas. The antibody has been tested to work effectively in several techniques such as Immunofluorescence, Western Blot, Fluorescent Activated Cell Sorting (FACS), and Immunohistochemistry (IHC).

Commercial Applications

• Developing cancer biomarker.

• Developing cell sorting assays (*e.g.* FACS).

• Immunofluorescence, Western Blotting, and Immunohistochemistry for CEA.

• Developing prognostic assays for cancer.

Competitive Advantages: Tested to bind CEA and can be used in different Immunological Techniques such as Immunofluorescence, Western Blot, Fluorescent Activated Cell Sorting (FACS), and Immunohistochemistry (IHC).

Materials Available: 1 vial of Hybridoma cell line (B1.1).

Inventors: Jeffrey Schlom and David Colcher (NCI).

Related Publications

1. D. Colcher *et al.* (1983) [PubMed: 6365268].

2. D. Stramignoni *et al.* (1983) [PubMed: 6852972].

Patent Status: "The Generation of Monoclonal Antibody (MAb) B1.1 and Its Reactivity to Human Tumors," HHS Reference No. E–272–2010/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Sabarni Chatterjee, Ph.D.; 301–435–5587; *chatterjeesa@mail.nih.gov.*

Novel Compounds That Specifically Kill Multi-Drug Resistant Cancer Cells

Description of Technology: One of the major hindrances to successful cancer chemotherapy is the development of multi-drug resistance (MDR) in cancer cells. MDR is frequently caused by the increased expression or activity of ABC transporter proteins in response to the toxic agents used in chemotherapy. The increased expression or activity of the ABC transporter proteins causes the toxic agents to be removed from cells before they can act to kill the cell. As a result, research has generally been directed to overcoming MDR by inhibiting the activity of ABC transporters, thus causing the chemotherapeutic agents to remain in the cell long enough to exert their effects. However, compounds that inhibit ABC transporter activity often elicit strong and undesirable side-effects due to the inhibition of ABC transporter function in normal cells, thereby restricting their usefulness as therapeutics.