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.

Monoclonal Antibodies for Rare Diseases

Description of Technology: Available for licensing are three monoclonal antibodies (mAb) that bind with high specificity and affinity to the tumor cell surface antigen tyrosine kinase-like orphan receptor 1 (ROR1). ROR1 is expressed in chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL), two incurable B-cell malignancies that are designated as rare diseases by NIH's Office of Rare Diseases Research. Therapeutics for rare diseases can qualify for orphan drug status and receive expedited review by the FDA. Currently, there are no therapeutic mAbs that target CLL or MCL but not healthy cells.

Investigators from the National Cancer Institute developed chimeric antibodies that selectively target ROR1 malignant B-cells but not normal B-cells. Additionally, this technology allows for mAb derivatives with potentially higher pharmacokinetic and/or pharmacodynamic activity, including humanized mAb in an IgG and IgM format, antibody-drug conjugates, immunotoxins, and bispecific antibodies. These three mAbs have been characterized in vitro for mediating antibody-dependent cellular cytotoxicity, complement-dependent cytotoxicity, apoptosis, and internalization. Results show that these mAbs bind with high specificity and affinity to three different epitopes on human ROR1, and ROR1-expressing primary CLL cells from untreated CLL patients and MCL cell lines. Moreover, as these antibodies selectively target ROR1, they can also be used to diagnose B-cell malignancies.

Applications:

- Antibody treatments for B–CLL and MCL
- Diagnostics for B–CLL and MCL

Advantages:

- Therapeutics that can qualify for an orphan drug status by the FDA and receive expedited FDA review
- Antibodies that selectively target malignant B-cells and not healthy cells

Development Status: The technology is currently in the pre-clinical stage of development.

Market:

- Global orphan drugs market reached $58.7 billion in 2006 and it is expected to reach $81.8 billion by 2011
- Biologic drugs account for over 60% of the orphan drug market with sales of $35.3 billion in 2006 and it is projected to be worth $53.4 billion by 2011

Inventors: Christoph Rader and Jiahui Yang (NCI)

Relevant Publication: Yang J et al. Therapeutic potential and challenges of targeting receptor tyrosine kinase ROR1 with monoclonal antibodies in B-cell malignancies. PLoS ONE 2011;6(6):e21018. Epub 2011 Jun 15. [PMID: 21698301]

Patent Status: U.S. Provisional Application No. 61/418,550 filed December 1, 2010 (HHS Reference No. E–039–2011/0–US–01)

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; Phone No.: 301–435–4633; E-mail Address: *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research, Experimental Transplantation and Immunology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize anti-ROR1 monoclonal antibodies and their derivatives. Please contact Dr. Christoph Rader at (301) 451–2235 or *raderc@mail.nih.gov* for more information.

Oral Vaccine for Inducing Mucosal Immunity

Description of Technology: Available for licensing is a micro/nanoparticle oral vaccine delivery system that specifically targets the large intestine for vaccine deposition and in situ immune activation, with minimal perturbation in the upper part of the gastrointestinal (GI) tract.

Vaccine delivery to the large intestine has been experimentally demonstrated as an effective means for inducing mucosal immunity against infections transmitted through the recto-genital mucosal area such as sexually transmitted disease as well as fungal and parasitic infections. In this system, the vaccine components are encapsulated by nanometer-sized particles to allow optimal uptake once it reaches the lumen and makes contact with the intestinal mucosal surface. To protect from premature degradation and uptake in the upper GI, these particles are coated within micrometer-sized particles. This coating is designed with a pH- and time-dependent release profile that is optimized for vaccine uptake to occur within the large intestine. This particular feature may also make this technology a potential delivery system for recto-colon cancer therapies.

Applications:

- Vaccine delivery system for inducing mucosal immunity against a variety of infections transmitted through the recto-genital mucosal area
- Potential delivery system for recto-colon cancer therapeutics
- Potential delivery system for recto-colon immunotherapies or controlled drug release

Advantages:

- Oral delivery provides a more practical and less invasive means of vaccine delivery to the large intestine compared to intrarectal or intracolorectal routes
- Delivery system can be used against a variety of diseases transmitted through the recto-genital mucosa
- Proof of concept has been demonstrated in vivo.

Development Status:

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

Market: Global vaccine market is expected to be worth an estimated $23.8 billion by 2012

Inventors: Qing Zhu (NCI), Jay A. Berzofsky (NCI), James Talton (Nanotherapeutics Inc.)

Relevant Publication: Manuscript submitted, under review.

Patent Status: HHS Reference Number E–132–2009/0 —

- US Application No. 61/238,361 filed 31 Aug 2009
- PCT Application No. PCT/US2010/047338 filed 31 Aug 2010

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov*.

Collaborative Research Opportunity: The Center for Cancer Research, Vaccine Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Oral Delivery of a Vaccine to the Large Intestine to Induce Mucosal Immunity. Please contact John Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: July 21, 2011.

Richard U. Rodriguez,

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

[FR Doc. 2011–18965 Filed 7–26–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 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., 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Sensation and Perception.

Date: August 17–18, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John Bishop, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, *bishopj@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; ADHD and Brain Development.

Date: August 19, 2011.

Time: 1 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call)

Contact Person: Samuel C. Edwards, PhD, Chief, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Kidney and Urological Diseases.

Date: August 24, 2011.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call)

Contact Person: Chantal A Rivera, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, MSC 7818, Bethesda, MD 20892, 301–435–1243, *riveraca@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 21, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–18969 Filed 7–26–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Molecular Neuroscience.

Date: August 5, 2011.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call)

Contact Person: Toby Behar, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, MSC 7850, Bethesda, MD 20892, (301) 435–4433, *behart@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 21, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–18968 Filed 7–26–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.