

93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 7, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-21894 Filed 9-12-16; 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: Oncology 1-Basic Translational Integrated Review Group, Tumor Cell Biology Study Section.

Date: October 5-6, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Charles Morrow, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, 301-408-9850, morrowcs@csr.nih.gov.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Molecular Neurogenetics Study Section.

Date: October 6-7, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott New Orleans, 555 Canal Street, New Orleans, LA 70130.

Contact Person: Mary G Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301-915-6301, marygs@csr.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group;

Dissemination and Implementation Research in Health Study Section.

Date: October 12-13, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Jessica Bellinger, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, bellingerjd@csr.nih.gov.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: October 12-13, 2016.

Time: 8:00 a.m. to 5:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435-1170, luow@csr.nih.gov.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Xenobiotic and Nutrient Disposition and Action Study Section.

Date: October 12, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Handlery Union Square Hotel, 351 Geary Street, San Francisco, CA 94102.

Contact Person: Martha Garcia, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, Bethesda, MD 20892, 301-435-1243, garciamc@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Surgical Sciences Biomedical Imaging and Bioengineering.

Date: October 12, 2016.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Jan Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, Bethesda, MD 20892, 301.402.9607, Jan.Li@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: September 7, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-21893 Filed 9-12-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 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 and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION CONTACT:

Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Title of invention: A SNP-based blood test for predicting breast cancer survival and determining treatment strategies.

Keywords: SNP Single Nucleotide Polymorphism Array Probe Breast Cancer.

Description of Technology

Metastasis is a primary cause of patient morbidity and mortality in solid tumors. Although recent advances in genomic technologies have provided major insights into tumor etiology, there is a significant lack of knowledge regarding the factors that contribute to metastasis.

Through studying the metastatic susceptibility of tumors, researchers at NCI's Laboratory of Cancer Biology and Genetics have discovered a select panel of single nucleotide polymorphisms (SNPs) and a method for predicting

breast cancer patient's survival. In this array, SNPs are analyzed from a patient's genomic DNA (gDNA); the result can be used to predict whether a patient is likely to respond to current breast cancer treatment strategies. This invention can reassure newly diagnosed patients that they have a high probability of responding to treatment and can also identify those patients that require alternative, more aggressive therapeutic strategies. Importantly, this invention has several advantages over the currently-offered gene expression-based breast cancer prognostic tests. Since this array can be completed following routine blood draw, rather than through a tumor biopsy, the samples are more stable, the process is quicker, simpler, less-invasive, and more cost-effective than current methods.

Potential Commercial Applications

- Identification of patients with higher susceptibility to tumor progression (*i.e.*, metastasis).
- Prediction of breast cancer survival (less than 10 years, for example) using array and methods.
- Personalization of patient treatment.

Value Proposition: Since the array processes DNA from blood rather than tissue from a standard biopsy or resection of a primary tumor, it is faster, simpler, more stable, more cost-efficient, and less-invasive because gDNA is more stable than tumor mRNA.

Development Stage: Pre-clinical (in vivo validation).

Inventor(s): Kent W. Hunter, Ph.D. (NCI), Howard H. Yang, Ph.D. (NCI), Maxwell P. Lee, Ph.D. (NCI).

Intellectual Property: HHS Reference No. E-082-2015/0-US-01

US Provisional Application 62/297,557 (HHS Reference No. E-082-2015/0-US-01) filed February 19, 2016 entitled "SNP-Based Assay to Predict Breast Cancer Survival".

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations for methods that provide significant improvements in examining additional SNPs for improved prognostics, and to evaluate whether the SNP signature is associated with overall cancer incidence or effective treatment strategies.

Contact Information: Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email hewesj@mail.nih.gov.

Dated: September 5, 2016.

John D. Hewes,

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016-21905 Filed 9-12-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

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SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 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 and/or co-development.

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SUPPLEMENTARY INFORMATION:

Technology description follows.

Title of invention: Immunotoxins with Increased Stability for Cancer Therapy.

Keywords: Recombinant Immunotoxin, RIT, Antibody, Mesothelin, Mesothelioma.

Description of Technology

Recombinant immunotoxins (RITs) are fusions of an antibody-based targeting moiety and a toxin. Pseudomonas exotoxin A (PE) is a bacterial toxin that has been used in several RITs evaluated in clinical

trials.^{1,2} Once the Fv portion of the immunotoxin binds to its target receptor, the immunotoxin is internalized by endocytosis. Following internalization, Furin cleavage is critically important for proper cytosolic shuttling of the immunotoxin. Early PE-containing RITs were effective, but also had issues of off-target toxicity.

To mitigate off-target toxicity of PE, the inventors removed specific sequences of domain II, and connected the Fv domain to domain III (PE24) by a furin linker peptide. These PE24-RITs are very active and better tolerated by mice. However, the PE24-containing RITs could potentially be cleaved and inactivated before internalization by cell surface furin or other proteases in the bloodstream or the tumor microenvironment, due to the absence of a key disulfide bond (lost after removal of domain II sequences).

Researchers at the National Cancer Institute's Laboratory of Molecular Biology (NCI LMB) developed and isolated several de-immunized, low toxicity, PE24-based RITs with a longer serum half-life. This was enabled by using a disulfide bond to protect the furin cleavage sequence (FCS). Collectively, the new RITs are designated "DS-PE24" immunotoxins. The goal of the disulfide bond is to protect the RIT from cleavage-based deactivation before internalization. The most active of these new RITs has longer serum half-life than an RIT without the disulfide bond, has the same anti-tumor activity, while remaining less cytotoxic *in vitro*. Currently, the inventors are working with mouse models to further develop the DS-PE24 RITs towards developing an anti-mesothelin RIT for treatment of mesothelin-expressing cancers, such as mesothelioma.

Potential Commercial Applications

- A more stable cancer therapeutic for currently used PE-coupled RITs, for example, anti-mesothelin PE-based immunotoxins.

Value Proposition

- Protection of the FCS by a disulfide bond results in more stable RIT, which can lead to fewer off-target effects.

Development Stage: *In-vivo*.

Inventor(s): Ira Pastan M.D. (NCI), *et al.*

Intellectual Property: United States Provisional Patent Application 62/323,668 (NIH Reference E-157-2016/0-US-01), entitled "New, More Stable

¹ Fitzgerald DJ, Kreitman R, et al. *Int J Med Microbiol.* 2004;293:577-582.

² Sampson JH, Akabani G, Archer GE, et al. *J Neurooncol.* 2003;65(1):27-35.