

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.

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: 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.

Immunotoxin Variants with a Disulfide Bond Protecting the Furin Cleavage Site.”

Related Technologies

- NIH Reference E–262–2005, entitled “Mutated *Pseudomonas* Exotoxins with Reduced Antigenicity”
- NIH Reference E–292–2007, entitled “Deletions in Domain II of *Pseudomonas* Exotoxin A that Reduce Non-Specific Toxicity”
- NIH Reference E–174–2011, entitled “*Pseudomonas* Exotoxin A with Less Immunogenic T-Cell and/or B-Cell Epitopes”
- NIH Reference E–263–2011, entitled “*Pseudomonas* Exotoxin A with Less Immunogenic B-Cell Epitopes”

Researchers at the NCI seek parties interested in licensing DS–PE24 RITs.

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: john.hewes@nih.gov.

Dated: September 5, 2016.

John D. Hewes,

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

[FR Doc. 2016–21906 Filed 9–12–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; 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 materials, 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 Library of Medicine Special Emphasis Panel; R01/R21/K01/K99 Conflicts.

Date: December 2, 2016.

Time: 11:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Zoe E. Huang, MD, Scientific Review Officer, Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968, 301–594–4937, huangz@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: September 7, 2016.

Michelle Trout,

Program Analyst, Office of the Federal Advisory Committee Policy.

[FR Doc. 2016–21898 Filed 9–12–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

**[FWS–R3–ES–2016–N153;
FXES11130300000–167–FF03E00000]**

Endangered and Threatened Wildlife and Plants; Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications for a permit to conduct activities intended to enhance the survival of endangered or threatened species. Federal law prohibits certain activities with endangered species unless a permit is obtained.

DATES: We must receive any written comments on or before October 13, 2016.

ADDRESSES: Send written comments by U.S. mail to the Regional Director, Attn: Carlita Payne, U.S. Fish and Wildlife Service, Ecological Services, 5600

American Blvd. West, Suite 990, Bloomington, MN 55437–1458; or by electronic mail to permitsR3ES@fws.gov.

FOR FURTHER INFORMATION CONTACT: Carlita Payne, (612) 713–5343.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973 (ESA), as amended (16 U.S.C. 1531 *et seq.*), prohibits certain activities with endangered and threatened species unless the activities are specifically authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A permit granted by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with U.S. endangered or threatened species for scientific purposes, enhancement of propagation or survival, or interstate commerce (the latter only in the event that it facilitates scientific purposes or enhancement of propagation or survival). Our regulations implementing section 10(a)(1)(A) of the ESA for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Applications Available for Review and Comment

We invite local, State, Tribal, and Federal agencies and the public to comment on the following applications. Please refer to the permit number when you submit comments. Documents and other information the applicants have submitted with the applications are available for review, subject to the requirements of the Privacy Act (5 U.S.C. 552a) and Freedom of Information Act (5 U.S.C. 552).

Permit Applications

Proposed activities in the following permit requests are for the recovery and enhancement of survival of the species in the wild.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE04397C	Giorgianna G. Auteri.	Indiana bat (<i>Myotis sodalis</i>), northern long-eared bat (<i>Myotis septentrionalis</i>), gray bat (<i>Myotis grisescens</i>).	Rangewide ...	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, radio-tag, release.	New.