

Licensing Contact: Michael Shmilovich, Esq.; 301-435-5019; shmilovm@mail.nih.gov

Collaborative Research Opportunity: The National Heart, Lung and Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize devices for pericardial interventional procedures. For collaboration opportunities, please contact Peg Koelble at 301-594-4095 or koelblep@nhlbi.nih.gov.

Pseudomonas Exotoxin A With Modified Furin Cleavage Site

Description of Technology: Immunotoxins kill cancer cells while allowing healthy, essential cells to survive. As a result, patients receiving immunotoxins are less likely to experience the deleterious side-effects associated with non-specific therapies such as chemotherapy. In order to make an effective immunotoxin, three components are generally required: A targeting domain, a furin cleavage site (FCS), and a toxic payload molecule (such as *Pseudomonas* exotoxin A (PE)). The purpose of the FCS is to allow the toxin domain to be processed by the target cell so that it can exert its toxic effect. This technology concerns the engineering of FCS in order to improve the efficacy of specific immunotoxins having distinct targeting domains. Several novel FCS have been generated which can be substituted for the native FCS in PE. By using specific FCS with different targeting moieties, it is possible to engineer an immunotoxin that is better suited to treating specific types of cancer.

Potential Commercial Applications

- Essential for the payload component of immunotoxins
- Treatment of any disease associated with increased or preferential expression of a specific cell surface receptor
- Specific diseases include hematological cancers, lung cancer (including mesothelioma), ovarian cancer, breast cancer, and head and neck cancers

Competitive Advantages

- Designing specific furin cleavage sites for particular immunotoxins can improve cleavage and enhance toxin efficacy, resulting in improved therapeutic effectiveness
- Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer non-specific side-effects and healthier patients

Development Stage: In vitro data available.

Inventors: Ira Pastan et al. (NCI).

Publications

1. Weldon JE, et al. Designing the furin-cleavable linker in recombinant immunotoxins based on *Pseudomonas* exotoxin A. *Bioconjug Chem.* 2015 Jun 17;26(6):1120-8. [PMID 25997032]
2. Weldon JE, et al. A protease-resistant immunotoxin against CD22 with greatly increased activity against CLL and diminished animal toxicity” *Blood.* 2009 Apr 16;113(16):3792-800. [PMID 18988862]

Intellectual Property: HHS Reference No. E-197-2015/0-US-01-US Provisional Application No. 62/163,667 filed May 19, 2015.

Related Technologies

- HHS Reference E-262-2005/0

- HHS Reference E-292-2007/0
- HHS Reference E-269-2009/0
- HHS Reference E-174-2011/0
- HHS Reference E-263-2011/0

Licensing Contact: David A. Lambertson, Ph.D.; 301-435-4632; lambertsond@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize *Pseudomonas* Exotoxin A with Modified Furin Cleavage Site. For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

Dated: August 31, 2015.

Richard U. Rodriguez,
Acting Director, Office of Technology Transfer, National Institutes of Health.
[FR Doc. 2015-21940 Filed 9-3-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent Commercialization License: Cerclage Annuloplasty Devices for Treating Mitral Valve Regurgitation

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a worldwide exclusive license to practice the inventions embodied in:

NIH Ref No.	Patent application No.	Filing date	Title
E-048-2009/0-US-01	61/157,267	March 4, 2009	Cerclage Locking Device And Delivery System.
E-048-2009/0-PCT-02	PCT/US2010/026245	March 4, 2010	Cerclage Locking Device And Delivery System.
E-048-2009/0-US-03	13/254,160	March 4, 2010	Cerclage Locking Device And Delivery System.
E-108-2010/0-US-01	61/383,061	September 15, 2010	Methods and Devices For Transcatheter Cerclage Annuloplasty.
E-108-2010/0-PCT-02	PCT/US2011/51748	September 15, 2011	Methods and Devices For Transcatheter Cerclage Annuloplasty.
E-108-2010/0-EP-03	11760945.3	September 15, 2011	Methods and Devices For Transcatheter Cerclage Annuloplasty.
E-108-2010/0-US-04	13/824,198	March 15, 2013	Methods and Devices For Transcatheter Cerclage Annuloplasty.

To Transmural Systems, LLC, a limited liability company incorporated under the laws of the State of Massachusetts and having its principle place of business in Andover, Massachusetts.

The contemplated exclusive license may be limited to cerclage annuloplasty devices for treating mitral valve regurgitation.

DATES: Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before October 5, 2015 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael Shmilovich, Esq. Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5019; Facsimile: (301) 402-0220; Email: shmilovm@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

E-048-2009

The invention relates to a device that can be used to non-invasively secure surgical suture loops when combined with a percutaneous delivery system. It has been shown to be effective in correcting mitral valve regurgitation (MVR) in an animal model. During the procedure, a guidewire is percutaneously conveyed to the atrium of the heart and is used to secure the "cerclage" suture encircling the mitral valve annulus, which is delivered using a delivery catheter. The locking device is advanced over the suture by the delivery catheter and it permanently secures the suture and maintains the tension on the annulus once the delivery system is removed. This locking device, in combination with the percutaneous procedure, allows for more complete coaptation of the valve leaflets and correction of MVR without the need for open heart surgery and its associated risks. The locking device is also adjustable, allowing the user to vary the tension on the suture if further tightening or loosening is required. It is also MRI compatible and all follow-up studies can be performed under MRI. This invention demonstrated its ability to correct MVR in animals where the locking device was observed to maintain the correct position and tension after implantation. This device has the potential to replace the traditional loop and knot method used for surgical correction of MVR, and may also be useful for other conditions that require permanently secured suture loops.

E-108-2010

The invention relates to techniques and devices for cardiovascular valve repair, particularly annuloplasty techniques and devices in which tensioning elements are positioned to treat regurgitation of the mitral valve or tricuspid valve. More specifically, the technology pertains to a new device for myocardial septal traversal ("cerclage reentry") that also serves to capture (ensnare) and externalize the traversing guidewire. The focus of the invention is to avoid a phenomenon in cardiac

surgery known as "trabecular entrapment." The device features an expandable and collapsible mesh deployed in the right ventricle to simplify capture of a reentering guidewire during transcatheter cerclage annuloplasty. The wire mesh exerts pressure against trabecular-papillary elements of the tricuspid valve to displace them against the right ventricular septal wall. By abutting the right ventricular reentry site of the cerclage guidewire, trabecular entrapment is avoided. The device comprises a shaft having a distal loop which provides a target in the interventricular myocardial septum through which a catheter-delivered tensioning system is guided. The loop ensnares the catheter-delivered tensioning system as it reenters the right ventricle or right atrium. The expandable and collapsible mesh is disposed within the right ventricle such that the catheter-delivered tensioning system is directed from the ventricular septum into the right ventricular cavity through only a suitable opening in the mesh and such that the catheter delivered tensioning system is captured or ensnared within the mesh opening.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404. Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 1, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015-21969 Filed 9-3-15; 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: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group Surgery, Anesthesiology and Trauma Study Section.

Date: October 7-8, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

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: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group Integrative Nutrition and Metabolic Processes Study Section.

Date: October 8-9, 2015.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Long Beach, 500 E 1st Street, Long Beach, CA 90802.

Contact Person: Gregory S Shelness, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 6156, Bethesda, MD 20892-7892, (301) 435-0492, shelnessgs@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Molecular and Cellular Endocrinology Study Section.

Date: October 8-9, 2015.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Long Beach, 500 East First Street, Long Beach, CA 90802.

Contact Person: John Bleasdale, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170