

*MedicalDevicesAdvisoryCommittee/
CirculatorySystemDevicesPanel/
ucm342357.htm.*

Dated: September 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-21815 Filed 9-12-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Evaluation License: Development of Antibody-Drug Conjugates Comprising Topoisomerase Inhibitors for the Treatment of Human Cancers

AGENCY: National Institutes of Health,
HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Provisional Patent Application No. 60/844,027 entitled, "Azonafide derived tumor and cancer targeting compounds," filed September 12, 2006 [HHS Ref. No. E-160-2006/0-US-01], PCT Application No. PCT/US2007/078233 entitled, "Azonafide derived tumor and cancer targeting compounds," filed September 12, 2007 [HHS Ref. No. E-160-2006/0-PCT-02], European Patent Application No. 7842310.0 entitled, "Azonafide derived tumor and cancer targeting compounds," filed September 12, 2007 [HHS Ref. No. E-160-2006/0-EP-03], and U.S. Patent Application No. 12/441,029 entitled, "Azonafide derived tumor and cancer targeting compounds," filed March 12, 2009 now US Patent No. 8,008,316 issued August 30, 2011 [HHS Ref. No. E-160-2006/0-US-04], and all related continuing and foreign patents/patent applications for the technology family, to Oncolinx, Inc. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to the development and use of the licensed patent rights as a component of an antibody-drug conjugate for the treatment of human cancers. Upon expiration or termination of the exclusive evaluation option license, Oncolinx will have the right to execute an exclusive patent

commercialization license which will supersede and replace the exclusive evaluation option license with no broader territory than granted in the exclusive evaluation option license and the field of use will be commensurate with the commercial development plan at the time of conversion.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before September 30, 2014 will be considered. **ADDRESSES:** Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Jennifer Wong, M.S., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4633; Facsimile: (301) 402-0220; Email: wongje@od.nih.gov.

SUPPLEMENTARY INFORMATION: The present technology provides compound formulation and method of use of improved derivatives of 2-[2'-(2-aminoethyl)-2-methyl-ethyl]-1,2-dihydro-6-methoxy-3H-dibenz-[de,h]isoquinoline-1,3-dione (herein referred to as azonafides), anthracene-based DNA intercalators that inhibit tumor growth. The synthesized azonafides can be attached to a ligand or antibody to recognize specific receptors on cancer cells and delivered as a targeted cytotoxic payload. The azonafides have been developed to allow for easy modification with different peptide linkers and antibodies, but also allow for rapid release once cleaved in lysosomes after delivery to the cancer cell enabling highly targeted attack of cancer cells. The azonafides have reduced toxicity and lower development of drug resistance.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive evaluation option license, and a subsequent exclusive patent commercialization license, may be granted unless within fifteen (15) days from the date of this published notice, the 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 part 404.

Any additional, properly filed, and complete applications for a license in the field of use filed in response to this

notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted 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 9, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014-21855 Filed 9-12-14; 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 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. 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.

FOR FURTHER INFORMATION CONTACT: 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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

A Novel Fusion Protein for Inhibiting HIV Budding

Description of Technology: Ubiquitin plays a critical role in HIV-1 budding. Vectors containing deubiquitin enzymes (DUBs) were constructed to deliver DUBs to HIV-1 production sites in living cells. The DUBs vectors comprise DUB cDNAs and cDNA expressing either HIV-1 gag, or the ESCRT protein TSG101.

Experimental data show that the fusion proteins expressed by the DUBs vectors retained their known protein-protein interactions and caused a significant and specific interruption of HIV-1 budding. The data suggest that the DUBs vectors could be used to inhibit HIV-1 infection or propagation in an individual. Thus, the DUBs vectors could potentially be used in high-risk individuals to prevent HIV-1 infection or as an adjunct therapy with known Anti-Retroviral Therapy (ART/HAART) in infected individuals.

Potential Commercial Applications:

- Prevention for HIV
- Treatment for patients infected with HIV
- Clinical research

Competitive Advantages:

- Use for both treatment and prevention
- No development of resistance to HIV

Development Stage: In vitro data available.

Inventors: Fadila Bouamr and Paola Sette (NIAID).

Publication: Sette P, et al. Ubiquitin conjugation to Gag is essential for ESCRT-mediated HIV-1 budding. *Retrovirology*. 2013 Jul 29;10:79 [PMID 23895345].

Intellectual Property: HHS Reference No. E-223-2014/0—U.S. Provisional Application No. 62/030,193 filed 29 July 2014.

Licensing Contact: John Stansberry, Ph.D.; 301-435-5236; stansbej@mail.nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize the DUBs vectors and/or the fusion proteins expressed by the vectors. For collaboration opportunities, please contact Fadilla Bouamr, Ph.D. at bouamrf@niaid.nih.gov.

Surgical Tool for Subretinal Tissue Implantation

Description of Technology: The invention pertains to a surgical tool for implanting a sheet of tissue into the eye in such a way that damage to the tissue and the eye during insertion and manipulation of the tissue is minimized. The device enables tissue to be released and delivered in a precise and controlled fashion. The device includes a hollow handle portion (e.g. a syringe) with a bore fashioned to convey fluid. An injector is fluidically coupled to the handle of the device and includes a flat triangular shaped tip that defines an aperture connected to the internal channel of the injector portion and

configured to enshroud a tissue for transplantation. Vacuum or pressure of a hydrostatic pump impels the fluid and enshrouded tissue into the tool and then into the eye. The tip of the surgical injector tool curved in a direction extending distally away from a handle of the surgical injector tool to better accommodate eye curvature.

Potential Commercial Applications:

- Ocular tissue transplantation
- Subretinal tissue transplantation
- Delivery of extended release drug pellets into subretinal space
- Ocular surgery
- Endothelial keratoplasty

Competitive Advantages:

- Precision of operation for surgeon (no extra moving parts)
- Instrument consists of separate disposable parts
- Controlled delivery
- Minimization of damage to the eye and transplanted tissue
- Ease of operation
- There is no available instrument capable to deliver tissue into subretinal space

Development Stage:

- Early-stage
- In vivo data available (animal)
- Prototype

Inventor: Arvydas Maminishkis (NEI).

Intellectual Property: HHS Reference No. E-192-2014/0—U.S. Provisional Application No. 62/023,289 filed 11 July 2014.

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

Collaborative Research Opportunity: The National Eye Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize ocular tissue transplantation device. For collaboration opportunities, please contact Matthew McMahon at 301-451-1610 or neitechtransfer@nei.nih.gov.

A Novel Demodulation System in X-ray Imaging

Description of Technology: In various x-ray imaging methods, including scattering correction and phase contrast imaging, intensity modulation in space is introduced into the projection images by the use of masks, gratings, or apertures. The present invention relates to a process to demodulate the modulation. The current demodulation processes are either to remove the modulation pattern through digital processing or to move the modulation pattern on the detector in a series of images that requires mechanical

movements of a component and tends to lose some information of the imaged object. The demodulation of the present invention can be realized with a relative movement between the projected image of the sample and the modulation pattern without having to move the modulation pattern. The demodulated images are free of the modulation pattern and have better clarity.

Potential Commercial Applications:

- Clinical diagnostic
- Research tools
- Security inspections

Competitive Advantages:

- Better clarity for images
- Simplify the demodulation method

Development Stage:

- In vitro data available
- In vivo data available (animal)

Inventors: Han Wen and Houxun Miao (NHLBI)

Publications:

1. David C, et al. Interferometer for quantitative phase contrast imaging and tomography with an incoherent polychromatic x-ray source. U.S. Patent No. 7,889,838 issued 15 Feb 2011. [<http://patft1.uspto.gov/netacgi/nph-Parser?patentnumber=7889838>].

2. Schusser S, Vogtmeier G. Non-parallel grating arrangement with on-the-fly phase stepping. x-ray system and use. PCT Application No. PCT/IB2010/055562 filed 02 Dec 2010. [<http://patentscope.wipo.int/search/en/WO2011070489>].

Intellectual Property: HHS Reference No. E-113-2013/0—U.S. Provisional Application No. 61/877,219 filed 12 Sep 2013.

Licensing Contact: John Stansberry, Ph.D.; 301-435-5236; stansbej@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 the technology. For collaboration opportunities, please contact Dr. Denise Crooks at crooksd@mail.nih.gov.

A Novel X-ray Grating To Enhance Phase Contrast Imaging

Description of Technology: The present invention relates to improving x-ray phase contrast imaging. The invention discloses a novel grating interferometer for phase contrast imaging with hard x-rays that overcomes limitations in the level of sensitivity by utilizing the advantages of far-field interferometers. The novel design and fabrication process can easily acquire absolute and differential

phase images of lightly absorbing samples.

Potential Commercial Applications:

- Clinical diagnostics
- Research tools

Competitive Advantages:

- More sensitivity
- Easier to fabricate images

Development Stage:

- In vitro data available
- In vivo data available (animal)

Inventor: Han Wen (NHLBI)

Publications:

1. Wen H. Boosting phase contrast with two-arm interferometers using sub-micron period gratings. Presentation, The Royal Society, London scientific discussion meeting: Taking x-ray phase contrast imaging into mainstream applications, February 11, 2013, London, UK.

2. Momose A, Fukuda J. Phase-contrast radiographs of nonstained rat cerebellar specimen. *Med Phys.* 1995 Apr;22(4):375–9. [PMID 7609717].

3. Clauser JF. Ultrahigh resolution interferometric x-ray imaging. U.S. Patent No. 5,812,629 issued 22 Sep 1998. [<http://patft1.uspto.gov/netacgi/nph-Parser?patentnumber=5812629>].

Intellectual Property: HHS Reference No. E–114–2013/0—U.S. Provisional Application No. 61/877,228 filed 12 Sep 2013.

Licensing Contact: John Stansberry, Ph.D.; 301–435–5236; stansbej@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 the technology. For collaboration opportunities, please contact Dr. Denise Crooks at crooksd@mail.nih.gov.

Dated: September 9, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014–21856 Filed 9–12–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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: National Cancer Institute Special Emphasis Panel; R01 Review.

Date: October 16, 2014.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 2W030, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Majed M. Hamawy, Ph.D., MBA, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W120, Bethesda, MD 20892–9750, 240–276–6457, mh101v@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Core Infrastructure and Methodological Research for Cancer Epidemiology Cohorts.

Date: October 21–22, 2014.

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

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W030–Oct 21, 5E030 Oct 22, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Kenneth L. Bielat, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W244, Rockville, MD 20850, 240–276–6373, bielatk@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Revisions Early Stage Informatics Technologies, Revisions Early Stage Informatics Technologies, Advanced Stage Informatics Technologies.

Date: November 4–5, 2014.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7E030–Nov 4, 5E030–Nov 5 Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Kenneth L. Bielat, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W244, Rockville, MD 20850, 240–276–6373, bielatk@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Imaging and Biomarkers for Early Cancer Detection.

Date: November 14, 2014.

Time: 11:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 1E030, Rockville, MD 20892–9750, (Telephone Conference Call).

Contact Person: Kenneth L. Bielat, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W244, Rockville, MD 20850, 240–276–66373, bielatk@mail.nih.gov.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/sep/sep.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS).

Dated: September 9, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–21854 Filed 9–12–14; 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: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Integrative Nutrition and Metabolic Processes Study Section.

Date: October 9, 2014.

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

Agenda: To review and evaluate grant applications.