

**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.

**DATES:** Only written comments and/or applications for a license which are received by the National Cancer Institute, Technology Transfer Center on or before January 29, 2016 will be considered.

**ADDRESSES:** 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](mailto:ncitechtransfer@mail.nih.gov).

**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](mailto: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:* Monoclonal Antibodies Fibroblast Growth Factor Receptor 4 (FGFR4) and Methods for Their Use.

*Description of Technology:* Rhabdomyosarcoma (RMS) is the most common soft tissue sarcoma in children and adolescents. Although current treatments for primary disease are relatively successful, metastatic RMS is generally accompanied by a dismal prognosis. Thus, the development new therapies for metastatic RMS provides a strong benefit to the advancement of public health.

Fibroblast Growth Factor Receptor 4 (FGFR4) is a cell surface protein that is highly expressed in RMS, and other cancers (including liver, lung, pancreatic, ovarian, and prostate cancers). Researchers in the National Cancer Institute's Genetics-Branch found that in RMS patients, high FGFR4 expression is often associated with

advanced-stage disease, rapid disease progression, and poor survival. The correlation between FGFR4 expression and highly aggressive RMS makes FGFR4 an attractive target for treatment of RMS. By targeting FGFR4 specifically, it may be possible to attack the cancer cells while leaving healthy, essential cells unaffected. This invention concerns the generation of several high-affinity monoclonal antibodies which can be used to treat FGFR4-related diseases. In particular, these antibodies have been used to generate antibody-drug conjugates (ADCs) and chimeric antigen receptors (CARs) which are capable of specifically targeting and killing diseased cells.

*Potential Commercial Applications:*

- Development of unconjugated antibody therapeutics
- Development of antibody-drug conjugates (ADCs) and recombinant immunotoxins (RITs)
- Development of chimeric antigen receptors (CARs) and T Cell Receptors (TCRs)
- Development of bispecific antibody therapeutics
- Development of Diagnostic Agents for detecting FGFR4-positive cancers

*Value Proposition:*

- High affinity and specificity of the antibodies allows more selective targeting of cancer cells, reducing the potential for side effects during therapy
  - Multiple antibodies available
- Development Stage:*

In vitro/Discovery

*Inventor(s):*

Javed Khan, M.D. (NCI), S. Baskar (NCI), R.J. Orientas (Lentigen Technology, Inc.)

*Publication(s):*

- “Comprehensive genomic analysis of rhabdomyosarcoma reveals a landscape of alterations affecting a common genetic axis in fusion-positive and fusion-negative tumors.” *Cancer Discov.* 2014 Feb;4(2):216–31. doi: 10.1158/2159-8290.CD-13-0639. Epub 2014 Jan 23.
- “Targeting wild-type and mutationally activated FGFR4 in rhabdomyosarcoma with the inhibitor ponatinib (AP24534)”. *PLoS One.* 2013 Oct 4;8(10):e76551. doi: 10.1371/journal.pone.0076551. eCollection 2013
- “Identification of FGFR4-activating mutations in human rhabdomyosarcomas that promote metastasis in xenotransplanted models.” *J Clin Invest.* 2009 Nov;119(11):3395–407. doi: 10.1172/JCI39703. Epub 2009 Oct 5.

—“Identification of cell surface proteins as potential immunotherapy targets in 12 pediatric cancers.” *Front Oncol.* 2012 Dec 17;2:194. doi: 10.3389/fonc.2012.00194. eCollection 2012.  
*Intellectual Property:*

HHS Reference No. E-264-2015/0-US-01

U.S. Provisional Patent Application No. 62/221,045 filed September 20, 2015 entitled “Monoclonal Antibodies Fibroblast Growth Factor Receptor 4 (FGFR4) and Methods for Their Use” [HHS Reference E-264-2015/0-US-01]  
*Licensing and Collaborative/Co-Development Research Opportunity:*

The National Cancer Institute seeks partners to license or co-develop the development new antibody-based therapies for metastatic Rhabdomyosarcoma (RMS).

*Contact Information:*

Requests for copies of the patent application or inquiries about licensing and/or research collaboration and co-development opportunities should be sent to John D. Hewes, Ph.D., email: [john.hewes@nih.gov](mailto:john.hewes@nih.gov).

Dated: December 22, 2015.

**Thomas M. Stackhouse,**

*Associate Director, Technology Transfer Center, National Cancer Institute.*

[FR Doc. 2015-32878 Filed 12-29-15; 8:45 am]

**BILLING CODE 4140-01-P**

## 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.

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**ADDRESSES:** 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](mailto:ncitechtransfer@mail.nih.gov).

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**SUPPLEMENTARY INFORMATION:**

*Title of invention:* Thalidomide/lenolidomide/pomalidomide analogs that inhibit inflammation, angiogenesis.

*Description of Technology:* Thalidomide and its close analogs (lenolidomide and pomalidomide) are widely used to treat a variety of diseases, such as multiple myeloma and other cancers, as well as the symptoms of several inflammatory disorders. However, thalidomide is known for its teratogenic adverse effects when first introduced clinically in the 1950s, and is associated with drowsiness and peripheral neuropathy. Hence, there is intense interest to synthesize, identify and develop safer analogs. Researchers at the National Institute on Aging's Drug Design and Development Section synthesized novel thalidomide analogs that demonstrate clinical potential without being teratogenic, as initially evaluated in *in vivo* zebrafish and chicken embryo model systems and in cell culture. These new compounds differentially provide potent anti-angiogenesis and/or anti-inflammatory action. The agents have potential for development of new cancer therapies and treatment of a number of neurological and systemic disorders involving chronic inflammation and elevated TNF-alpha levels.

*Potential Commercial Applications:*

- Cancer therapeutics
- Inflammatory disorders such as Crohn's disease, sarcoidosis, graft-versus-host disease, and rheumatoid arthritis
- Neuroinflammatory disorders (acute: Traumatic brain injury and stroke; chronic: Parkinson's disease, Alzheimer's disease, multiple sclerosis)

*Value Proposition:*

- Non-teratogenic
- Potent

*Development Stage:*

In Vitro/Discovery

*Inventor(s):*

Nigel H. Greig (NIA), Weiming Luo (NIA), David Tweedie (NIA), William Douglas Figg, Sr. (NCI), Neil Vargesson (Univ. Aberdeen, Scotland), and Shaunna Beedie (NCI & Univ. Aberdeen, Scotland)

*Intellectual Property:*

HHS Reference No. E-208-2015/0-US-01

U.S. Provisional Patent Application No. 62/235, 105, filed September 30, 2015, entitled "Thalidomide/lenolidomide/pomalidomide analogs that inhibit inflammation, angiogenesis"

*Licensing and Collaborative/Co-Development Research Opportunity:* The National Institute on Aging seeks collaborators to license or co-develop novel thalidomide analogs that demonstrate clinical potential without being teratogenic.

*Contact Information:* Requests for copies of the patent application or inquiries about licensing and/or research collaboration and co-development opportunities should be sent to John D. Hewes, Ph.D., email: [john.hewes@nih.gov](mailto:john.hewes@nih.gov).

*CFR Citation:* 35 U.S.C. 209 and 37 CFR part 404

Dated: December 22, 2015.

**Thomas M. Stackhouse,**

*Associate Director, Technology Transfer Center, National Cancer Institute.*

[FR Doc. 2015-32877 Filed 12-29-15; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute on Aging; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Rodent Tissue Bank.

*Date:* January 29, 2016.

*Time:* 12:30 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Kimberly Firth, Ph.D., National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-402-7702 [firthkm@mail.nih.gov](mailto:firthkm@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 23, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-32772 Filed 12-29-15; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Office of the Director; Amended Notice of Meeting**

Notice is hereby given of a correction in the meeting notice of the Big Data to Knowledge Multi-Council Working Group (BD2K) that was published in the **Federal Register** on Friday, December 11, 2015, 80 FRN 76996.

The date of the meeting is January 11, 2016. The time and meeting access codes remain the same.

A portion of the meeting is open to the public, 11 a.m. to 12:00 p.m. and is being held by teleconference only. No physical meeting location is provided for any interested individuals to listen to committee discussions. Any individual interested in listening to the meeting discussions must call: 1-866-692-3158 and use Passcode 2956317 for access to the meeting.

Dated: December 23, 2015.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-32768 Filed 12-29-15; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as