



BILLING CODE: 4140-01-P

DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing and Co-Development

AGENCY: National Institutes of Health.

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.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute, Technology Transfer Center on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] 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.

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: 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):

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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

US 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.

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National Cancer Institute

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