



This document is scheduled to be published in the Federal Register on 08/16/2016 and available online at <http://federalregister.gov/a/2016-19419>, and on FDsys.gov

BILLING CODE: 4140-01-P

DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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.

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: Human Monoclonal Antibodies Targeting Glypican-2 in Neuroblastoma

Keywords: Glypican-2, GPC2, Antibody, Immunotoxin, Recombinant Immunotoxin, RIT, Chimeric Antigen Receptor, CAR, Antibody-drug Conjugate, ADC, bispecific antibody, neuroblastoma

Description of Technology:

Neuroblastoma is a rare pediatric cancer that affects one in every hundred thousand children under the age of fifteen in the United States. Current standards of care are chemotherapy and surgery, followed by stem-cell treatments, radiation and anti-ganglioside antibody therapy, which yield an average three-year survival rate of 10-45%. This demonstrates a need for more effective therapies.

Glypican-2 (GPC2) is a cell surface protein that has been shown to be preferentially expressed on numerous pediatric cancers, including neuroblastoma. Due to this preferential expression, GPC2 represents a potential candidate for targeted therapy.

Researchers at the National Cancer Institute's Laboratory of Molecular Biology (NCI LMB) have developed and isolated several single domain monoclonal human antibodies against GPC2. This technology covers the naked GPC2 antibodies as well as their use as targeting domains in recombinant immunotoxins (RITs) and chimeric antigen receptors (CARs). RITs (using clones LH1, LH4, or LH7) and CARs (using LH7) have shown

specific killing activity against GPC2-expressing cells, suggesting that these candidates may be further developed as therapeutics.

The technology has been validated with *in-vitro* studies (human anti-GPC2 RITs and CARs can bind to, and kill, GPC2-positive tumor cells) and the researchers are currently developing mouse models to further develop GPC2-targeted therapies.

Potential Commercial Applications:

- Therapeutic applications include: unconjugated antibodies, and use as targeting moieties for immunoconjugates such as CARs, ADCs, immunotoxins, and bispecific antibodies
- Diagnostic agent for detecting and monitoring target-expressing malignancies

Value Proposition:

- First to market potential – No current clinical trials with GPC2-targeted therapies
- Human antibody with high specificity and binding to targets results in less non-specific cell killing, therefore fewer potential side-effects for the patient
- Small size of single domain antibodies enhances stability, solubility, and target recognition

Development Stage:

In-vitro

Inventor(s):

Mitchell Ho (NCI), *et al.*

Intellectual Property:

US Provisional Application 62/369,861 (HHS Reference No. E-211-2016/0-US-01) filed August 2, 2016, entitled “Human Monoclonal Antibodies Targeting Glypican-2 in Neuroblastoma”

Collaboration Opportunity:

Researchers at the NCI seek parties interested in licensing or co-developing GPC2 antibodies and/or conjugates.

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: August 8, 2016

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[FR Doc. 2016-19419 Filed: 8/15/2016 8:45 am; Publication Date: 8/16/2016]