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:

Therapeutic antibody-drug conjugates targeting CD56-positive tumors

Description of Technology:

CD56, also known as neural cell adhesion molecule (NCAM), is a glycoprotein that plays an important role in normal physiological functions. It is expressed in low levels in normal cells such as neurons, glia, skeletal muscle and natural killer cells but is highly expressed on a variety of cancerous cells including neuroblastoma, small-cell lung cancer, and multiple myeloma. In neuroblastoma, patients undergo a very aggressive treatment regimen that still results in a high mortality rate. Many neuroblastomas have increased expression of CD56 which represents a possible therapeutic target for these aggressive and hard to treat cancers.

Researchers at the National Cancer Institute's Cancer and Inflammation Program, in collaboration with the Children's Hospital of Philadelphia (CHOP), have developed antibody-drug conjugates (ADC) that incorporate one of two novel human CD56 antibodies, known as m900 and m906, in combination with a known cytotoxic drug, pyrrolobenzodiazepine (PBD). Other PBD-ADCs have demonstrated the ability to overcome resistance in some multi-drug resistant cancers which could present additional benefits for the ADCs of the current invention. The m900 and m906 ADCs have been shown to induce cell death and CD56 down regulation *in vitro* in four different CD56-positive neuroblastoma cell lines. Preliminary studies in animals have also shown

promising results, and additional *in vivo* work is ongoing.

Potential Commercial Applications:

- Therapeutic for the treatment of neuroblastoma
- Therapeutic for the treatment of other CD56-positive cancers including small cell lung cancer, multiple myeloma, pancreatic cancer, ovarian cancer, acute myeloid leukemia, NK-T lymphoma, and neuroendocrine cancer

Value Proposition:

- Fully human antibodies (m900 or m906) targeting CD56 may offer improved properties over the humanized antibody IMGN901

Development Stage:

Pre-clinical (in vivo validation)

Inventor(s):

Dimiter S. Dimitrov (NCI), Yang Feng (NCI), Zhongyu Zhu (NCI), John M. Maris (Children's Hospital of Philadelphia)

Intellectual Property:

HHS Reference No. E-221-2015/0-US-01. US Provisional Application No. 62/199,707, filed July 31, 2015 entitled "ANTIBODY-DRUG CONJUGATES FOR TARGETING CD56-POSITIVE TUMORS"

Publications:

Feng, Y, et al. Differential killing of CD56-expressing cells by drug-conjugated human antibodies targeting membrane-distal and membrane-proximal non-overlapping epitopes. mAbs, 2016; 24:1-12. DOI: 10.1080/19420862.2016.1155014

Related Technologies: E-142-2014 (CD56-targeting antibodies and related CARs)

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations for development of antibody-drug conjugates for the treatment of cancer.

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.

Date: June 2, 2016

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John D. Hewes

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute

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