BILLING CODE: 4140-01-P

DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing and Collaboration

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 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:

Genetically Engineered Mouse-Derived Allograft for Use in Preclinical Studies of Metastatic Melanoma Therapies

Keywords: Melanoma, GDA, Allograft, Genetically Engineered Mouse, immunological response

Description of Technology:

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.

Before testing drugs in humans, drug developers are required to demonstrate a reasonable expectation of safety and efficacy by performing so-called pre-clinical studies. A key element of such trials is the use of animal models, typically mice or rats that are selected for demonstrating hallmarks of a given disease. For cancer research, while many mouse models exist to simulate the response of the cancer to a particular drug, all of the current models have some limitations in their ability to fully predict the concomitant physiological or immunological response that might result when the drug progresses to clinical trials. This is problematic both in models in which the cancer spontaneously develops in the animal as well as models in which cancerous cells or tumors, i.e. allografts (derived from cells of the same organism) or xenografts (derived from cells of different organism, usually humans), are transplanted into an otherwise cancer-free animal.

To address these issues, researchers at NCI developed a means of more closely simulating in mouse models both melanoma cancer itself and the resulting physiological and immunological response by creating a genetically engineered mice (GEM)-derived allograft (GDA). This allograft both resembles human-like melanoma and has features that will stimulate a normal immunological response in the mouse. Thus, when transplanted into a host, the resulting tumor-containing mouse may be used to test conventional cancer therapies (e.g., chemotherapy and radiotherapy), targeted drugs (e.g., kinase inhibitors), and immunotherapies with an expectation that the response in the mouse will more closely mimic the types of responses expected in humans if the therapy progresses to clinical trials. Further this melanoma-based GDA approach may represent a new standard for building or improving preclinical models of other types of cancer.

Potential Commercial Applications:

- This is a novel mouse allograft model that provides a preclinical model of human-like advanced-stage melanoma.
- This allograft model may be useful for preclinical testing of conventional therapies, targeted therapies, and immunotherapies.

Value Proposition:

- Hgf-tg;Cdk4R24C C57BL/6 mouse-derived melanoma allograft with humanized pathogenetics allows adoption of clinically relevant procedures and endpoints, facilitating clinical translation.
- Features a constitutively activated MET/MAPK pathway and disrupted CDKN2A pathway.
- Expresses typical diagnostic markers of human melanoma such as DCT and TRP1.
- Exhibits progression patterns relevant to human disease.

Development Stage:

Basic (Target ID)

Inventor(s):

Chi-Ping Day, Glenn T. Merlino, Zoe Weaver Ohler, Rajaa El Meskini, Terry A. Van Dyke (all of NCI), and Thomas Tüting (University Hospital Bonn)

Intellectual Property:

HHS Reference Number E-291-2015/0. This is a Research Tool. Following the policy of the National Institutes of Health, patent protection will not be sought.

Publications:

1. Day CP, *et al*. "Glowing head" mice: a genetic tool enabling reliable preclinical image-based evaluation of cancers in immunocompetent allografts. PLoS One 2014; 9(11):e109956. [PMID 25369133]
2. Day CP, *et al*. Preclinical mouse cancer models: a maze of opportunities and challenges. Cell. 2015;163(1):39-53. [PMID 26406370]

Contact Information:

Inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

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