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: Novel metastatic serous epithelial ovarian cancer (SEOC) genetically engineered mouse models, cell lines, and orthotopic models based on Rb, p53 and/or Brca 1/2 inactivation useful for biomarker discovery and preclinical testing.

Description of Technology:

The high mortality rate from ovarian cancers can be attributed to late-stage diagnosis and lack of effective treatment. Despite enormous effort to develop better targeted therapies, platinum-based chemotherapy still remains the standard of care for ovarian cancer patients, and resistance occurs at a high rate. One of the rate limiting factors for translation of new drug discoveries into clinical treatments has been the lack of suitable preclinical cancer models with high predictive value.

NCI CAPR has developed Tri-allelic K18-T121$^{tg/+}$/Brca1$^{fl/fl}$/p53$^{fl/fl}$ SEOC GEM Model, GEM-derived SEOC orthotopic mouse model, and biological materials derived therefrom, with several key histopathologic, immunophenotypical, and genetic features of human SEOC. SEOC GEMs were utilized to create orthotopic immunocompetent transplant models, and to generate synchronized cohorts of mice suitable for preclinical studies. NCI CAPR conducted studies that determine these models are tractable for use in routine efficacy studies and demonstrate the utility of these models in evaluating the potential efficacy of novel therapeutics for ovarian cancer.

Potential Commercial Applications:

- These models serve as a foundation for preclinical research and evaluation of efficacy of novel therapeutics for ovarian cancer.
- The GEM models described here can be used to develop cell lines and allograft models for evaluating drug potency relative to Brca1 mutation status.
- These mouse models provide the opportunity for evaluation of effective therapeutics, including prediction of differential responses in Brca1-wild type and Brca1–deficient tumors and development of relevant biomarkers.

Value Proposition:

- Novel resource for evaluating disease etiology and biomarkers, therapeutic evaluation, and improved imaging strategies in epithelial ovarian cancer
- Similarity to human ovarian cancer based on transcriptional profiling
- Suitable preclinical cancer models with high predictive value.

Development Stage:

Pre-clinical (in vivo validation)

Inventor(s):

Simone Difilippantonio, Terry Van Dyke, Zoe Weaver Ohler, Ludmila Szabova, Sujata Bupp, Yurong Song, Chaoying Yin

Intellectual Property:

Research use--no patent protection will be sought

Publications:

1. Szabova L, Yin C, Bupp S, et al. Perturbation of Rb, p53 and Brca1 or Brca2 cooperate in inducing metastatic serous epithelial ovarian cancer. *Cancer research*. 2012;72(16):4141-4153.

2. Szabova L, Bupp S, Kamal M, et al. Pathway-Specific Engineered Mouse Allograft Models Functionally Recapitulate Human Serous Epithelial Ovarian Cancer. Katoh M, ed. *PLoS ONE*. 2014;9(4):e95649.

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations for the commercialization of agents for the treatment of SEOC.

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.

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John D. Hewes

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