Dated: January 29, 2014.

Keisha Shropshire,

Project Clearance Officer, NIMH, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing 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.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Tumor Infiltrating Lymphocytes From Human Papillomavirus-Positive Tumors for the Treatment of Cancer

Description of Technology: Human papillomaviruses (HPV) cause anogenital and oropharyngeal cancers, and these malignancies express viral oncoproteins that can be recognized by T cells. When HPV-associated cancers spread they are incurable and difficult to palliate with existing treatments.

Tumor infiltrating lymphocytes (TIL) have been used successfully to treat advanced stage malignant melanoma, however their use has been primarily limited to this disease. This technology describes a novel TIL therapy for treating HPV-associated cancers. The NIH inventors have found TIL can be grown from HPV positive tumors at grade and scale suitable for clinical use and that they can recognize the HPV oncoproteins that drive transformation and survival of cancer cells. The inventors have initiated a clinical trial for the treatment of advanced HPV positive cancers that are refractory to standard chemotherapy using HPV–TIL. Early results of the clinical trial suggest that HPV–TIL has activity in chemotherapy-refractory advanced disease for which no standard treatment options are available.

Potential Commercial Applications: HPV–TIL therapy is a novel treatment approach that may mediate long-lasting tumor regression from a single dose of cells.

Competitive Advantages: Early clinical results suggest that HPV–TIL has activity in chemotherapy-refractory advanced disease for which no standard treatment options are available.

Development Stage: In vitro data available (human)

Inventors: Christian Hinrichs and Steven A. Rosenberg (NCI)

Publications:

1. Piersma SJ, *et al.* Human papilloma virus specific T cells infiltrating cervical cancer and draining lymph nodes show remarkably frequent use of HLA–DQ and –DP as a restriction element. Int J Cancer 2008 Feb 1;122(3):486–94. [PMID 17955486]

2. de Vos van Steenwijk PJ, *et al.* An unexpectedly large polyclonal repertoire of HPV-specific T cells is poised for action in patients with cervical cancer. Cancer Res. 2010 Apr 1;70(7):2707–17. [PMID 20233872]

Intellectual Property: HHS Reference No. E–494–2013/0—US Provisional Application No. 61/846,161 filed 15 July 2013

Related Technology: HHS Reference No. E–495–2013/0—US Provisional Application No. 61/846,167 filed 15 July 2013

Licensing Contact: Whitney A. Hastings; 301–451–7337; *hastingw@mail.nih.gov*

Improved Culture Medium for Stem Cell Maintenance and Differentiation

Description of Technology: A novel low protein culture medium with defined chemical components that allows pluripotent stem cell maintenance and differentiation is disclosed. The present technology also provides for production of high quality cardiac cells from human embryonic and induced pluripotent stem cells in chemically defined medium conditions. Human pluripotent stem cells, including human embryonic stem cells and human induced pluripotent stem cells, can be propagated indefinitely while still retaining the capacity to differentiate into all somatic cell types, and are a potentially inexhaustible supply of human cells. The capacity to sustain survival at high density is critical for maintaining consistent stem cell cultures and avoiding the development of abnormal stem cells, and for proper stem cell differentiation. Also, it is essential to have high quality stem cells for all personalized cellular therapies. NIH investigators developed a low protein medium that supports the proliferation and differentiation of stem cells comprising one or more of a volume expander, a lipid mix and a growth factor modulator. Also, the investigators have used the new medium to produce high quality cardiac cells from human embryonic and induced pluripotent stem cells.

Potential Commercial Applications:

- Improved defined medium to grow, maintain and differentiate stem cells.
- This medium can be used to develop culture systems that could be used to generate specific cell types for potential clinical applications.

Competitive Advantages: This new medium could significantly improve progenitor cell derivation from embryonic stem cells and induced pluripotent stem cells and could have great usage in future translational applications.

Development Stage:

- Early-stage
- In vitro data available
- In vivo data available (animal)

Inventors: Guokai Chen and Yongshun Lin (NHLBI)

Intellectual Property: HHS Reference No. E–089–2013/0—US Provisional Application No. 61/879,840 filed 19 September 2013

Licensing Contact: Sury Vepa, Ph.D., J.D.; 301–435–5020; *vepas@mail.nih.gov*

Collaborative Research Opportunity: The National Heart, Lung, and Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Stem Cell Culture Medium. For collaboration opportunities, please contact Peg Koelble at *koelblep@nhlbi.nih.gov.*

Dated: February 10, 2014.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014–03083 Filed 2–12–14; 8:45 am]

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