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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: 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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

HbF Induction Therapy for Sickle Cell Disease and Thalassemias

Description of Technology: Sickle cell disease and thalassemia are hereditary disorders marked by the disruption in the pathways responsible for carrying oxygen to red blood cells. Symptoms associated with these disorders include anemia, jaundice, and severe pain. It has been shown that mutations during the development of fetal to adult hemoglobin can contribute to a delay in red blood cell maturity underlying sickle cell disease. As a result, there has been an increased focus on treatments that promote the induction of fetal hemoglobin (HbF) to improve clinical symptoms and ameliorate the severity of the diseases. Researchers at the National Institute of Diabetes and Digestive and Kidney Diseases have identified methods of increasing fetal hemoglobin by increasing the expression of Lin28 or decreased expression of let-7 micro-RNAs. The lead inventor and colleagues have developed novel lentiviral expression vectors containing hemoglobin regulators under the control of erythroid-specific promoters that can be used to increase Hbf expression without affecting the maturity of red blood cells. In addition, they have found, through the use of tough decoy inhibition of Let-7 micro-RNAs, a selection of Let-7 genes with greater involvement in HbF expression. This technology could lead to development of novel HbF induction therapies that reactivate and reduce the aberrant pathologies associated with human sickle-cell anemia and beta thalassemia.

Potential Commercial Applications:

- Ex vivo and in vivo therapeutics for treatment of sickle-cell anemia and beta thalassemias.

- Potential use in combination with other transduction methods for unique therapeutic strategies.

Competitive Advantages:

- Reduced production of symptom-associated adult hemoglobin.
- Lin28 overexpression at defined stage of hematopoietic cell development.
- Therapeutic increases in patient HbF expression at lower viral titers than current direct transduction methods.

- Improved safety and reduced toxicity as a result of erythroid-specific expression.

Development Stage:

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

Inventors: Jeffery L. Miller, Yuanwei T. Lee, Jaira F. de Vasconcellos, Colleen K. Byrnes (all of NIDDK)

Intellectual Property: HHS Reference No. E-249-2014/0 - US Provisional Application No. 62/046,247 filed September 5, 2014

Related Technology: HHS Reference No. E-456-2013/2 - PCT Application No. PCT/US2013/067811 filed October 31, 2013, which published as WO 2014/200557 on December 18, 2014

Licensing Contact: Vince Contreras, Ph.D.; 301-435-4711;

contrerasv@mail.nih.gov

Collaborative Research Opportunity: The National Institute of Diabetes and Digestive and Kidney Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Marguerite J. Miller at millermarg@nidDK.nih.gov or 301-496-9003.

T Cell-Based Adoptive Transfer Immunotherapy for Polyomavirus-Associated Pathologies

Description of Technology: Available for licensing are methods to generate T cells responsive to multiple polyomaviruses. The resulting T cell populations could be useful in treating immunosuppressed individuals with polyomavirus infections or polyomavirus-associated pathologies such as Merkel cell carcinoma (MCC), polyomavirus-associated nephropathy (PVAN), hemorrhagic cystitis, progressive multifocal leukoencephalopathy (PML), and trichodysplasia spinulosa (TS). The methods could also be used to restore polyomavirus-specific immunity in immunocompromised individuals.

Potential Commercial Applications: Immunotherapy for immunosuppressed individuals with polyomavirus-associated pathologies.

Competitive Advantages: Methods allow development of polyomavirus antigen-specific T cells.

Development Stage:

- Early-stage
- In vitro data available

Inventors: John A. Barrett (NHLBI), Dhanalakshmi Chinnasamy (NHLBI), Pawel J. Muranski (NHLBI), Christopher B. Buck (NCI)

Intellectual Property: HHS Reference No. E-166-2014/0 - US Application No. 62/075,726 filed November 5, 2014

Related Technologies:

- HHS Reference No. E-168-2011
- HHS Reference No. E-549-2013

Licensing Contact: Patrick McCue, Ph.D.; 301-435-5560;

mccuepat@od.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 methods to generate T cells responsive to multiple polyomaviruses. For collaboration opportunities, please contact Dr. Vincent Kolesnitchenko at kolesniv@nhlbi.nih.gov.

⁸⁹Zr-Oxine Complex for In Vivo PET Imaging of Labelled Cells and Associated Methods

Description of Technology: This technology relates to a Zirconium-89 (⁸⁹Zr)-oxine complex for cell labeling, tracking of labeled cells by whole-body positron emission tomography/computed tomography (PET/CT) imaging, and associated methods. A long half-life of ⁸⁹Zr (78.4 hours), high sensitivity of PET and absence of background

signal in the recipient enable tracking cells over a week using low levels of labeling radioactivity, without causing cellular toxicity. The ^{89}Zr -oxine complex is synthesized quickly by mixing components at room temperature and produces high yields. Cell labeling is achieved by a short, room temperature incubation. The ^{89}Zr -oxine complex is capable of labeling a wide range of cell types of therapeutic or pathogenic relevance (natural, disease, engineered cells), independent of factors such as cell cycle or receptor expression. The label is retained during cell division. ^{89}Zr -oxine labeled cells can also be easily cross labeled (for example, optically or magnetically) for multi-modality imaging and analysis. Labeled cell migration and kinetics can be analyzed and quantified in vivo over a week, improving research strategies and ability to develop and improve cell therapies and diagnostics.

Potential Commercial Applications: Cell therapies and diagnostics.

Competitive Advantages: Simple preparation, broadly applicable cell label, high resolution imaging and monitoring over period of a week, low toxicity, easily combined with labeling technologies and cell therapies.

Development Stage: In vivo data available (animal).

Inventors: Noriko Sato (NCI), Haitao Wu (NHLBI), Gary L. Griffiths (NCI), Peter L. Choyke (NCI)

Publications:

1. Sato N, et al. Generation and use of long-lasting cell labeling agent for positron emission tomography (PET) imaging. J Nucl Med. May 2014; 55 (Supplement 1):273.

2. Sato N, et al. ^{89}Zr -oxine complex positron emission tomography (PET) cell imaging for monitoring cell-based therapies. Radiology, 2015, In press.

Intellectual Property: HHS Reference No. E-080-2014/0 - US Patent Application No. 61/973,706 filed April 1, 2014

Licensing Contact: Edward (Tedd) Fenn; 424-297-0336; Tedd.fenn@nih.gov

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize cell labeling, cell tracking, cell trafficking, cell-based therapy, PET imaging. For collaboration opportunities, please contact John D. Hewes, Ph.D. at john.hewes@nih.gov or 240-276-5515.

Dated: February 18, 2015.

Richard U. Rodriguez,
Acting Director,
Office of Technology Transfer,
National Institutes of Health.

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