[Billing Code 4140-01-P]

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. 207 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.

Lentiviral Vectors with Dual Fluorescence/Luminescence Reporters

Description of Technology: Twelve lentiviral vectors that express both fluorescent and luminescent markers as a single fusion protein under various gene promoters were constructed. Vectors have been developed previously to monitor tumors or tumor cells via bioluminescence or fluorescence alone. However, bioluminescence is not sensitive enough to sort individual tumor cells and fluorescence cannot be used effectively to view internal tumors. By combining the two reporters into a single fusion protein, the tumor can be effectively visualized within the animal as well as sorted from non-tumor cells for post-necropsy experiments. The added advantage of bioluminescent visualization allows for *in vivo* experiments that more closely simulate the biological development of tumors in organs rather than at the surface of the skin. Additionally, since twelve different vectors with different gene promoters were developed, they can be tested in individual tumor models to find the best vector for visualizing that particular tumor cell line. The vectors are able to sustain long-term expression of both visualization markers, depending on the cell type and promoter in each vector.

Potential Commercial Applications:

• The vectors will be extremely useful for experiments in which both *in vivo* and *in vitro* analysis is desired.

• The vectors can also be used for screening cancer cell lines and in tumor models for reporter gene activity.

• The vectors can be useful in drug development.

Competitive Advantages:

• The bioluminescent marker allows for effective visualization of deep (non-surface) tumors in mice.

• The fluorescence label permits efficient sorting of tumor cells from normal (non-labeled) cells after tumors are excised from the mice.

• The vectors allow in vivo experiments that more closely simulate the biological development of tumors in organs rather than at surface of skin.

• The vectors sustain long-term expression.

Development Stage:

• Early-stage

• Pre-clinical

• In vitro data available

• In vivo data available (animal)

Inventors: Dominic Esposito, Chi-Ping Day, Glenn Y. Merlino (NCI)

Publication: Day CP, et al. Lentivirus-mediated bifunctional cell labeling for in vivo melanoma study. Pigment Cell Melanoma Res. 2009 Jun;22(3):283-95. [PMID 19175523]

Intellectual Property: HHS Reference No. E-132-2011/0 – Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Sury Vepa, J.D., Ph.D.; 301-435-5020; vepas@mail.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 dual luminescent/fluorescent vectors. For

collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

Epigenetic Factors Associated with the Development of Age-related Macular Degeneration

Description of Technology: Recent studies have demonstrated genetic associations between Age-related Macular Degeneration (AMD) and specific genes. In the case of identical twins in which only one twin develops AMD, a direct genetic cause seems unlikely. NIH researchers explored the epigenetic mechanisms that control the pathogenesis of AMD. A DNA methylation study identified sites on selected gene promoters that can potentially serve as markers to distinguish patients likely to develop AMD from those less likely to develop the disease. The strongest association was found in the IL17RC gene and later studies confirmed this association, first in siblings that were discordant for AMD and then in AMD patients as compared with age-matched controls.

Potential Commercial Applications: Diagnosis of Age-related Macular Degeneration.

Competitive Advantages: This technology is potentially a more sensitive means of diagnosing patients with AMD.

Development Stage: In vitro data available

Inventors: Lai Wei, Robert Nussenblatt, Baoying Liu, Chi-Chao Chan (NEI)

Publication: Wei L, et al. Hypomethylation of the IL17RC promoter associates with age-related macular degeneration. Cell Rep. 2012 Nov 29;2(5):1151-8. [PMID 23177625]

Intellectual Property: HHS Reference No. E-075-2011/0 –

• US Application No. 61/435,989 filed 25 Jan 2011

• PCT Application No. PCT/US2012/022511 filed 25 Jan 2011

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