Computerized Contingency Management, Ecological Momentary Assessment, and a Protocol Workflow System,'' Drug and Alcohol Review, 28(1):3–11, January 2009.

Intellectual Property: HHS Reference No. E–266–2014/0—Software. No patent protection is being sought.

Contact Information: Vio Conley, M.S.; NCI Technology Transfer Center; Phone: 240–276–5531; Email: *conleyv@mail.nih.gov.*

Keywords: Software, Clinical Information System, Research Information System, Medical Decision Support System (DSS), Electronic Hospital Records (EHR), Physicians Order Entry (POE), Pharmacy Information System, Laboratory Information Management (LIM), Biospecimen Tracking System, Substance abuse, Drug addiction, Mental health, mPAL, HuRIS.

Optimized Gene Therapy Vector for the Treatment of Glycogen Storage Disease Type Ia

Description of Technology: NIH researchers have developed an adeno-associated viral (AAV) vector for the treatment of glycogen storage disease type Ia (GSD-Ia). GSD-Ia is an inherited disorder of metabolism associated with life-threatening hypoglycemia, hepatic malignancy, and renal failure caused by the deficiency of glucose-6-phosphatase-alpha (G6Pase-alpha or G6PC). This new AAV vector that expresses human G6Pase-alpha directed by the tissue-specific human G6PC promoter/enhancer incorporates two improvements: (1) It expresses a variant of G6Pase-alpha with enhanced enzymatic activity; (2) it is codon optimized to achieve higher enzyme expression levels and enhanced enzymatic activity.

Current therapy, which primarily consists of dietary modification, fails to prevent long-term complications in many patients, including growth failure, gout, pulmonary hypertension, renal dysfunction, osteoporosis, and hepatocellular adenomas (HCA). Gene therapy-based techniques, which directly address the underlying genetic deficiency driving the disorder, offer the prospect of long-term remission in patients with GSD-Ia.

Potential Commercial Applications: Gene therapy vector for the treatment of GSD-Ia.

Competitive Advantages:

- Protein coding sequence modified for enhanced enzymatic activity.
- Codon optimized for increased enzyme expression in target organs.

Inventor: Janice J. Chou (NICHD)

Development Stage: In vivo data available (animal).

Publications:

1. Lee YM et al. Prevention of hepatocellular adenoma and correction of metabolic abnormalities in murine glycogen storage disease type Ia by gene therapy. Hepatology 2012 Nov;56(5):1719–29. [PMID 22422504].

2. Lee YM, et al. The upstream enhancer elements of the G6PC promoter are critical for optimal G6PC expression in murine glycogen storage disease type Ia. Mol Genet Metab. 2013 Nov;110(3):275–80. [PMID 23856420].

Intellectual Property: HHS Reference No. E–039–2015/0–US–01—US Provisional Patent Application 62/096,400 filed December 23, 2014.

Related Technologies: HHS Reference No. E–552–2013/0—US Provisional Patent Application No. 61/908,861 filed November 26, 2013; PCT Application No. PCT/US2014/067415 filed November 25, 2014.

Licensing Contact: Surekha Vathyam, Ph.D.; 301–435–4076; *vathyams@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Child Health and Human Development is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize gene therapy vectors for the treatment of glycogen storage disease type Ia. For collaboration opportunities, please contact Joseph M. Conrad, III, Ph.D., J.D. at *jmconrad@mail.nih.gov.*

Dated: September 25, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–24987 Filed 10–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Miniature Serial Sectioning Microtome for Block-Face Imaging

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to Carl Zeiss Microscopy GmbH, which is located in Germany, to practice the inventions embodied in the following patent applications:

1. US Provisional Application 61/991,929, filed May 12, 2014 (E–121–2014/0–US–01)
2. PCT Application PCT/US2015/030359, filed May 12, 2015 (E–121–2014/0–PCT–02)

The patent rights in these inventions have been assigned to the United States of America.

The prospective start-up exclusive license territory may be worldwide and the field of use may be limited to microtomes for scanning electron microscopes (SEMs) or light microscopes for life science applications.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before November 2, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Susan Ano, Ph.D., NINDS Technology Transfer and Development Branch, 31 Center Drive, Suite 8A52, MS2540, Bethesda, MD 20892; Telephone: (301) 435–5515; Email: *anos@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: A microtome device is used in a variety of microcopy techniques to remove very thin (*e.g.,* in the tens of nanometers range) portions from the top of a sample between successive images. This technology discloses a design for a microtome device that offers several unique features and advantages over commercially available microtomes. A prototype of the microtome has been built and demonstrated to work with a serial block-face scanning electron microscopy in order to serially collect ultrathin sections from plastic embedded biological tissues. This microtome design allows for a sample to be cut at a location removed from the electron beam axis, reducing interference from debris and allowing imaging at a greater range of working distances. This microtome device is lightweight and easy to install utilizing the built-in stage of existing microscopes such that a sample's position and orientation can be controlled along three-axes of rectilinear translation and two axes of rotation. This microtome design utilizes a diamond blade coupled to both the base plate and an actuator to control the movement of the blade in a direction perpendicular to the exposed surface of the pedestal, while producing an output

signal that indicates the blade location with respect to the base plate. Advantageously, this allows for a stage coupled pedestal to be moved accurately from an imaging location on the beam axis to a cutting location off the beam axis.

The prospective start-up exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated start-up exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 28, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–24994 Filed 10–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of a Start-up Exclusive Commercial License Agreement: Development of MHC Class II Restricted T Cell Epitopes From the Cancer Antigen, NY ESO–1, for the Treatment of Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404.7, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an start-up exclusive commercial license to Immunova Therapeutics, Inc., which is located in Houston, Texas, to practice the inventions embodied in the following patent applications and applications claiming priority to these applications:

E–090–2000

1. U.S. Provisional Patent Application No. 61/179,004 filed January 28, 2000 entitled ''MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO–1'' (HHS Ref No. E–090–2000/0–US–01);
2. U.S. Provisional Patent Application No. 60/237,107 filed September 29, 2000 entitled ''HLA–DP Restricted CD4+ T Cell Epitopes from the Cancer Antigen, NY ESO–1'' (HHS Ref No. E–227–2000/0–US–01 was combined with E–090–2000/0–US–01 at the PCT stage, creating the E–090–2000/1 technology family and associated applications);
3. PCT Application No. PCT/US01/02765 filed January 26, 2001 entitled ''MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO–1'' (HHS Ref No. E–090–2000/1–PCT–01);
4. Canadian Patent No. 2398743 issued June 23, 2015 entitled ''MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO–1'' (HHS Ref No. E–090–2000/1–CA–02);
5. Australian Patent No. 785151 issued January 18, 2007 entitled ''MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO–1'' (HHS Ref No. E–090–2000/1–AU–03);
6. Japanese Patent No. 5588363 issued August 1, 2014 entitled ''MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO–1'' (HHS Ref No. E–090–2000/1–JP–12);
7. U.S. Patent No. 7,619,057 issued November 17, 2009 entitled ''MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO–1'' (HHS Ref No. E–090–2000/1–US–06);
8. U.S. Patent No. 8,754,046 issued June 17, 2014 entitled ''MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO–1'' (HHS Ref No. E–090–2000/1–US–07);
9. U.S. Patent Application No. 12/568,134 filed September 28, 2009 entitled ''MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO–1'' (HHS Ref No. E–090–2000/1–US–013);
10. European Patent Application No. 10010354.8 filed January 26, 2001 entitled ''MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY ESO–1'' (HHS Ref No. E–090–2000/1–EP–10);

The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective start-up exclusive commercial license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights to develop, manufacture, distribute, sell and use NY–ESO–1 based vaccines and cell therapy products for the treatment of NY–ESO–1-positive cancers.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before October 19, 2015 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702; Telephone: (240) 276–5530; Facsimile: (240) 276–5504; Email: *chatterjeesa@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: NY–ESO–1 is a known tumor antigen which is expressed on a broad range of tumor types, including melanoma, breast, bladder, ovarian, prostate, head and neck cancers, neuroblastoma, and small cell lung cancer. The above-referenced inventions embody the identification of a number of novel immunogenic peptide epitopes, and analogs thereof, which are derived from the NY–ESO–1 tumor antigen. Specifically, this technology describes novel MHC Class II restricted epitopes of NY–ESO–1 which are recognized by CD4+ T cells. It also embodies the identification of two additional immunogenic peptide epitopes of NY–ESO–1. The latter two epitopes are presented by HLA–DP4, a prevalent MHC Class II allele present in 43–70% of Caucasians. The inventors also determined that the DP allele is highly associated with the NY–ESO–1 antibody production. In addition, one of these epitopes has dual HLA A2 and DP4 specificity, thereby it has the potential to generate both CD4+ and CD8+ tumor specific T cells. These epitopes may be of great value as prophylactic and/or therapeutic cancer vaccines or cell therapy products for use against a number of common cancers.

The prospective start-up exclusive commercial license is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective start-up exclusive commercial license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

Any additional, properly filed, and complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive commercial license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.