

*Development Status:* Preclinical data is available at this time.

*Inventors:* Yasutaka Hoshino and Albert Z. Kapikian (NIAID).

*Related Publications:*

1. Y Hoshino, RW Jones, J Ross, AZ Kapikian. Porcine rotavirus strain Gottfried-based human rotavirus candidate vaccines: construction and characterization. *Vaccine* 2005 May 31;23(29):3791–3799.

2. M Gorziglia, K Nishikawa, Y Hoshino, K Taniguchi. Similarity of the outer capsid protein VP4 of the Gottfried strain of porcine rotavirus to that asymptomatic human rotavirus strains. *J Virology*, 1990 Jan;64(1):414–418.

*Patent Status:* U.S. Provisional Application No. 60/698,572 filed 11 Jul 2005 (HHS Reference No. E–056–2005/0–US–01)

*Licensing Status:* Available for non-exclusive or exclusive licensing.

*Licensing Contact:* Chekesha Clingman, Ph.D.; 301/435–5018; [clingmac@mail.nih.gov](mailto:clingmac@mail.nih.gov).

#### **Adoptive T-Cell Transfer After Lymphodepletion Promotes Tumor Regression**

*Description of Technology:* Available for licensing is a method of adoptive cell transfer (ACT) immunotherapy. Since its first description, ACT is now being developed for the supportive treatment of a variety of infectious diseases and cancer.

Current ACT methods to treat cancer are based on the ex vivo selection of lymphocytes with high avidity for recognition of tumor antigens, and their activation and numerical expansion before re-infusion to the autologous tumor-bearing host. The current invention improves ACT by including a pre-treatment regimen to ensure permissive conditions in the host for in vivo proliferation of the transferred cells. Specifically, the immune system is suppressed by pre-treatment with lymphodepleting chemotherapy. Two separate clinical trials have demonstrated that using this approach, ACT can induce lasting tumor shrinkage.

Lymphodepleting chemotherapy followed by ACT resulted in tumor shrinkage of at least 50 percent in 6 out of 13 treated patients suffering from refractory melanoma. Several patients remained cancer free for more than a year after treatment. The usefulness of combined ACT and lymphodepleting therapy for cancer treatment was confirmed when this study was extended to include 35 melanoma patients. Eighteen of the 35 patients (51%) responded to the treatment,

including 3 patients who experienced ongoing complete disappearance of cancer and 15 patients had tumor shrinkage of at least 50 percent with a mean duration of almost a year after treatment. In a recent clinical trial that is not yet published, using a modified protocol to treat 23 patients, a similar response rate (56%) was seen.

This approach to ACT offers a potentially significant improvement in the treatment of many types of cancer. In addition, this method might be applicable in treating other diseases such as AIDS, immunodeficiency, or other autoimmunity for which immune effector cells can impact the clinical outcome.

*Inventors:* Mark E. Dudley, Steven A. Rosenberg, John R. Wunderlich (NCI).

*Publications:*

1. Dudley ME, et al. “Adoptive cell transfer therapy following non-myeloablative but lymphodepleting chemotherapy for the treatment of patients with refractory metastatic melanoma.” *J Clin Oncol*. 2005 Apr 1;23(10):2346–2357.

2. Dudley ME, et al. “Cancer regression and autoimmunity in patients after clonal repopulation with antitumor lymphocytes.” *Science*. 2002 Oct 25;298(5594):850–854.

*Patent Status:* U.S. Provisional Application No. 60/408,681 filed 06 Sep 2002 (HHS Reference No. E–275–2002/0–US–01); PCT Application No. PC/US03/27873 filed 05 Sep 2003, which published as WO 2004/021995 on 18 Mar 2004 (HHS Reference No. E–275–2002/1–PCT–01); U.S. Patent Application No. 10/526,697 filed 05 May 2005 (HHS Reference No. E–275–2002/1–US–02).

*Licensing Status:* Available for exclusive and non-exclusive licensing.

*Licensing Contact:* Michelle A. Booden, Ph.D.; 301/451–7337; [boodenm@mail.nih.gov](mailto:boodenm@mail.nih.gov).

*Collaborative Research Opportunity:* The NCI Surgery Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize ACT therapy. Please contact Steven A. Rosenberg, M.D., Ph.D. at 301/496–4164 for more information.

Dated: July 28, 2006.

**Steven M. Ferguson,**  
*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 06–6872 Filed 8–11–06 8:45 am]

**BILLING CODE 4140–01–M**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, 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.

**ADDRESSES:** 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.

#### **Hollow Waveguide Laser Delivery System for Digital Particle Image Velocity**

##### *Description of Technology*

Available for licensing and commercial development is an all-hollow-waveguide laser delivery system used for effective digital particle image velocimetry (DPIV) illumination. The System incorporates two key optical hollow waveguide components: An uncoated funnel-shaped hollow glass taper for a direct laser-to-taper coupling and a flexible hollow core waveguide for precise high-peak-power laser delivery. The principle of operation of the uncoated hollow taper is based on grazing-incidence effect. The optical taper is used for direct lens-free launching of laser radiation including from powerful lasers into fibers and waveguides. Because of the mutual action of the direct parallel laser excitation, the mode coupling process and mode filtering effect, the hollow taper serves as a mode converter that transforms the highly multimode profile of the input laser emission into a high-quality Gaussian-shaped profile at the taper output. Moreover, because of the lower power density of the output laser beam and its high causality profile, the

taper ensures higher damage threshold for the delivery waveguide in comparison to the conventional lens laser-to-fiber coupling. To improve the high-peak-power delivery capability of the proposed allow-hollow-waveguide DPIV illumination system, instead of a conventional solid-core fiber link, we have used a cyclic olefin polymer (COP)-coated hollow glass waveguide which is designed to minimize the waveguide attenuation losses at a typical DPIV laser wavelength of 532-nm. This waveguide provides a significantly higher laser power delivery capability and higher damage threshold. The all-hollow-waveguide DPIV laser delivery system offers essential advanced features over conventional bulk-optics-based delivery techniques in terms of formatting thin (0.5–1.0 mm), wide (10 mm or wider) and uniform laser illumination sheet; high-peak-power laser delivery without damaging effects (> 1 GW/cm<sup>2</sup>), flexibility, miniaturization, simplified alignment, immunity to external influence (including vibrations and angular laser beam drift), and safe and confined laser delivery.

#### Applications

2. Optics; Particle imaging; Velocimetry.

#### Market

4. Illumination, high peak laser powered delivery.

#### Inventors

6. Ilko K. Ilev, Ronald A. Robinson, Ronald W. Waynant (FDA).

#### Publications

1. IK Ilev et al., "Grazing-Incidence-Based Hollow Taper for Infrared Laser-to-Fiber Coupling," *Applied Physics Letters*, Vol. 74, 1999, pp. 2921–2923.

2. IK Ilev et al., "Uncoated Hollow Taper as a Single Optical Funnel for Laser Delivery," *Review of Scientific Instruments*, Vol. 70, 1999, pp. 3840–3843.

3. IK Ilev et al., "Ultraviolet Laser Delivery Using an Uncoated Hollow Taper," *IEEE Journal of Quantum Electronics*, Vol. 36, 2000, pp. 944–948.

4. IK Ilev et al., "Attenuation Measurement of Infrared Optical Fibers Using a Hollow-Taper-Based Coupling Method," *Applied Optics*, Vol. 39, 2000, pp. 3192–3196.

5. RA Robinson et al., "Design and Optimization of a Flexible High-Peak Power Laser-to-Fiber Coupled Illumination System Used in Digital Particle Image Velocimetry," *Review of Scientific Instruments*, Vol. 75, 2004, pp. 4856–4862.

#### Patent Status

8. U.S. Provisional Application No. 60/730,866 filed 28 Oct 2005 (HHS Reference No. AE-015-2006/0-US-01).

#### Licensing Status

10. Available for non-exclusive or exclusive licensing.

#### Licensing Contact

Michael A. Shmilovich, Esq.; 301/435-5019. [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov). <<mailto:shmilovm@mail.nih.gov>>

#### Collaborative Research Opportunity

The Food and Drug Administration's Center for Devices and Radiological Health is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact the inventors at 301/827-4685 for more information.

Dated: July 28, 2006.

#### Steven M. Ferguson,

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

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### Model Th1 Clone Producing IFN-gamma and IL-2

#### Description of Technology

Available for licensing is the A.E7 T cell clone, a model Th1 clone described in Matis et al., *J Immunol.* 1983 Apr 130(4):1527–1535 [*PubMed abs*] and *J Immunol.* 1983 Sept 131(3):1049–1055 [*PubMed abs*]. This clone has been further utilized as a model for studying T cell clonal anergy.

#### Potential Applications of Technology

2. Model Th1 clone capable of making IFN-gamma and IL-2

4. Model T cell clone for studying T cell clonal anergy

#### Inventors

Ronald H. Schwartz et al. (NIAID).  
Louis A. Matis (NIAID).  
Dan L. Longo (NCI).  
Toby T. Hecht (NCI).

#### Patent Status

HHS Reference No. E-214-2006/0—Research Tool.

#### Licensing Status

Available for non-exclusive licensing.

#### Licensing Contact

Susan Ano, Ph.D.; Phone: (301) 435-5515; Email: [anos@mail.nih.gov](mailto:anos@mail.nih.gov).

Dated: July 31, 2006.

#### Steven M. Ferguson,

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

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