DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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 contacting Catherine Joyce, Ph.D., J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3821; telephone: 301/496–7056 ext. 258; fax: 301/402–0220; e-mail: *joycec@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Methods of Generating Human CD4+ Th1 Cells

Dr. Daniel H. Fowler et al. (NCI).

[DHHS Reference No. E–335–01/0 filed 31 Aug 2001]

This technology pertains to the identification of specific culture conditions that yield human CD4+ T cells highly enriched for Th1 cytokine production. Recently, techniques have been developed that enable the *in vitro* expansion of mixed populations of T cells (CD4+ T-cells and CD8+ T-cells) using magnetic microbeads to which monoclonal antibodies to CD3 and CD28 have been attached. This technology is being developed commercially as the Xcellerate'' technology by Xcyte Therapies, Inc., Seattle, Washington.

The instant invention is directed to the use of the 3/28 bead-stimulated expansion of CD4+ cells, under specific culture conditions, to yield highly pure populations of Th1 cells. The reported conditions permit the production of large numbers of pure Th1 CD4+ cells from human CD4+ cells. Autologous populations of pure Th1 CD4+ cells may be useful for anti-cancer therapy and/or to enhance the immune response against infectious agents.

Methods of Generating Human CD4+ Th2 Cells

Dr. Daniel H. Fowler et al. (NCI).

[DHHS Reference No. E–114–01/0 filed 02 Jul 2001]

This technology pertains to the identification of specific culture conditions that yield a high purity of Th2 cells. Recently, techniques have been developed that enable the *in vitro* expansion of mixed populations of T cells (CD4+ T-cells and CD8+ T-cells) using magnetic microbeads to which monoclonal antibodies to CD3 and CD28 have been attached. This technology is being developed commercially as the Xcellerate'' technology by Xcyte Therapies, Inc., Seattle, Washington.

The instant invention is directed to the use of the 3/28 bead-stimulated expansion of CD4+ cells, under specific culture conditions, to yield highly pure populations of Th2 cells. The reported conditions permit the production of large numbers of pure Th2 CD4+ cells from human CD4+ cells. This technology is potentially applicable for the treatment of several medical conditions. Particularly, research regarding the clinical application of using pure Th2 cells for reducing graft-versus-host disease (GVHD) during allogeneic stem cell transplantation (used in the treatment of leukemia and lymphoma) has proceeded to the stage of Phase I clinical trials.

Transforming Growth Factor-Beta (TGF-Beta) Antagonist Selectively Neutralizes ''Pathological'' TGF-Beta

Drs. Lalage Wakefield and Yu-an Yang (NCI).

[DHHS Reference No. E–059–01/0 filed 21 Jun 2001]

This technology pertains to the use of a soluble transforming growth factor-beta (TGF-beta) antagonist (SR2F) for the suppression of metastasis. The SR2F antagonist is composed of the soluble extracellular domain of the type II TGF-beta receptor fused to the Fc domain of human IgG. In accordance with the invention, it has been discovered that overexpression of the SR2F antagonist in transgenic mice significantly protects against experimentally induced metastasis without inducing the negative effects associated with loss of TGF-beta function in the TGF-beta knock out mice. Lifetime exposure to the antagonist did not result in any increase in spontaneous or induced tumorigenesis, and there was no evidence for significant manifestations of autoimmune disease or increase in inflammatory lesions. The inventors speculate that this apparent ability of SR2F to discriminate between ''physiological'' and ''pathological'' TGF-beta relates to the relative accessibility of the two forms of TGF-beta, with only pathological TGF-beta being accessible to the antagonist.

Dated: February 20, 2002.

Jack Spiegel,

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

[FR Doc. 02–4831 Filed 2–27–02; 8:45 am]

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Production of Adeno-Associated Virus in Insect Cells

Robert M Kotin et al. (NHLBI)

Serial No. 09/986,618 filed 09 Nov 01

Licensing Contact: Susan Rucker; 301/496–7735 ext 245; e-mail: ruckers@od.nih.gov

The invention, described and claimed in this patent application, relates to the field of production of recombinant adeno-associated virus (rAAV). More particularly, the invention relates to systems for producing rAAV in a baculovirus-based system. The systems