Application: Intervertebral disc bio-constructs and electrospinning methods for fabrication of the discs.

Developmental Status: Prototype devices have been fabricated and preclinical studies have been performed.

Inventors: Wan-Ju Li, Leon Nesti, Rocky Tuan (NIAMS).

Patent Status:

U.S. Provisional Application No. 60/847,839 filed 27 Sep 2006 (HHS Reference No. E–309–2006/0–US–01).

U.S. Provisional Application No. 60/848,284 filed 28 Sep 2006 (HHS Reference No. E–309–2006/1–US–01).

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

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

Bioreactor Device and Method and System for Fabricating Tissue

Description of Technology: Available for licensing and commercial development is a millifluidic bioreactor system for culturing, testing, and fabricating natural or engineered cells and tissues. The system consists of a millifluidic bioreactor device and methods for sample culture. Biologic samples that can be utilized include cells, scaffolds, tissue explants, and organoids. The system is microchip controlled and can be operated in closed-loop, providing controlled delivery of medium and biofactors in a sterile temperature regulated environment under tabletop or incubator use. Sample perfusion can be applied periodically or continuously, in a bidirectional or unidirectional manner, and medium re-circulated.

Advantages:

The device is small in size, and of conventional culture plate format.

Provides the ability to grow larger biologic samples than microfluidic systems, while utilizing smaller medium volumes than conventional bioreactors. The bioreactor culture chamber is adapted to contain sample volumes on a milliliter scale (10 [mu]L to 1 mL, with a preferred size of 100 [mu]L), significantly larger than chamber volumes in microfluidic systems (on the order of 1 [mu]L). Typical microfluidic systems are designed to culture cells and not larger tissue samples.

The integrated medium reservoirs and bioreactor chamber design provide for, (1) concentration of biofactors produced by the biologic sample, and (2) the use of smaller amounts of exogenous biofactor supplements in the culture medium. The local medium volume (within the vicinity of the sample) is less than twice the sample volume. The total medium volume utilized is small, preferably 2 ml, significantly smaller than conventional bioreactors (typically using 500–1000 mL).

Provides for real-time monitoring of sample growth and function in response to stimuli via an optical port and embedded sensors. The optical port provides for microscopy and spectroscopy measurements using transmitted, reflected, or emitted (e.g., fluorescent, chemiluminescent) light. The embedded sensors provide for measurement of culture fluid pressure and sample pH, oxygen tension, and temperature.

Capable of providing external stimulation to the biologic sample, including mechanical forces (e.g. fluid shear, hydrostatic pressure, matrix compression, microgravity via clinorotation), electrical fields (e.g., AC currents), and biofactors (e.g., growth factors, cytokines) while monitoring their effect in real-time via the embedded sensors, optical port, and medium sampling port.

Monitoring of biologic sample response to external stimulation can be performed non-invasively and non-destructively through the embedded sensors, optical port, and medium sampling port. Testing of tissue mechanical and electrical properties (e.g., stiffness, permeability, loss modulus via stress or creep test, electrical impedance) can be performed over time without removing the sample from the bioreactor device.

The bioreactor sample chamber can be constructed with multiple levels fed via separate perfusion circuits, facilitating the growth and production of multiphasic tissues.

Application: Cartilage repair and methods for making tissue-engineered cartilage.

Development Stage: Electrospinning method is fully developed and cartilage has been synthesized.

Inventors: Juan M. Taboas (NIAMS), Rocky S. Tuan (NIAMS), et al.

Patent Status:

U.S. Provisional Application No. 60/701,186 filed 20 Jul 2005 (HHS Reference No. E–042–2005/0–US–01).

PCT Application No. PCT/US2006/028417 filed 20 Jul 2006, which published as WO 2007/012071 on 25 Jan 2007 (HHS Reference No. E–042–2005/0–PCT–02).

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

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

Dated: October 22, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–21100 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Public Teleconference Regarding Licensing and Collaborative Research Opportunities for: Treatment of Autoimmune and Allergic Disorders (NIAID)

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

ACTION: Notice.

Technology Summary

These technologies relate to compositions and methods useful in treating autoimmune diseases generally, and Multiple Sclerosis specifically.

Technology Description

Scientists at the NIH have discovered a method for the treatment or prevention of autoimmune diseases, allergic or atopic disorders, and graft rejections. This method selectively induces apoptosis of disease causing T lymphocytes, while sparing the majority of T-cells. Cell death is achieved by the cyclical administration of disease specific antigens and IL–2.

Further, the NIH scientists have developed compositions and methods for clinical assessment, diagnosis and treatment of Multiple Sclerosis (MS). The compositions are molecules related to the human proteolipid protein (PLP), and the 21.5 kDA fetal isoform of human myelin basic protein (MBP), including nucleic acids and polypeptides. The polypeptides can be used to assay T-cells for responsiveness to MBP and PLP epitopes. They are further useful as therapeutic agents for treating MS by inducing T-cell apoptosis. The inventors have demonstrated that treatment with MP4, a protein chimera of MBP, and a modified form of PLP, termed PLP4, prevented clinical symptoms of MS in both rodent and non-human primates. They have also completed primate toxicity tests demonstrating the compounds are non-toxic.

Novel application of these methods described in these technologies include:

Infusion of autoimmune disease antigen peptides reduces the severity of allergic diseases.

Pre-immunization prior to engraftment with foreign tissues prolongs graft survival time.

With molecular identification of allergy-evoking antigens, it will be possible to immunize in cycle with IL–4 to induce apoptosis of T cells involved in allergic disorders.

It is envisioned that autoimmune diseases such as multiple sclerosis, rheumatic fever, lupus and others can be treated using IL–2 and the relevant peptide to cause apoptosis of the T cells responsible for the disease.

The fact that interleukin-2 and 4 participates in the death of a subpopulation of T lymphocytes cells capable of causing diseases while leaving the majority of T lymphocyte cells substantially unaffected enhances the therapeutic value of these inventions.

The use of a novel therapeutic agent, i.e., MP4, in the treatment of MS.

Competitive Advantage of Our Technology

Autoimmune diseases result from a dysfunction of the immune system in which the body attacks its own organs, tissues and cells. More than 80 clinically distinct autoimmune diseases have been identified, including: type-1 diabetes (300,000–500,000 cases in the U.S.); systemic lupus erythematosus (240,000 cases in the U.S.); multiple sclerosis (250,000 to 350,000); rheumatoid arthritis (2.1 million cases in the U.S.); inflammatory bowel diseases, including both Crohn's disease and ulcerative colitis (800,000 in the U.S.); hemolytic anemia; Graves' disease; scleroderma; psoriasis (2% to 4% of the U.S. population); Sjörgen's syndrome, Immune Thrombocytopenic Purpura (ITP). Collectively, autoimmune diseases afflict 14–22 million Americans or 5% to 8% of the United States population.

Treatment of autoimmune diseases generally involves suppressing the immune system, and depending on the particular disease, different treatments are used. To demonstrate the diversity among these treatments consider the following: immunosuppressants such as azathioprine, chlorambucil, cyclophosphamide, cyclosporine or methostrexate are among the category of therapeutic agents employed in treating some autoimmune diseases. Corticosteroids such as prednisone are also used for both their immunosuppressive effect and anti-inflammatory activities. Tumor Necrosis Factor Antagonists, such as Etanercept and Infliximab are also used in treating some autoimmune disorders. Finally, Platelet transfusion and Plasmapheresis are used to treat a few autoimmune disorders.

MS is an autoimmune disease affecting the central nervous system, characterized by disseminated patches of demyelination in the brain and spinal cord, resulting in multiple and varied neurologic symptoms and signs, usually with remissions and exacerbations. The currently approved drugs for MS are different recombinant forms of interferons and are primarily used for the treatment of RRMS. Antegren, which blocks cellular adhesion, is currently in the pipeline and will be useful in treating SPMS patients.

There is a current theoretical patient population of approx 368,000 patients with MS in the U.S. and approx. 450,000 in Western Europe. Considering an estimated yearly growth rate of this market of 0.9%, this number will increase to approximately 390,000 by 2010 and approximately 400,000 by 2013 in the U.S. alone.

The total U.S. sales in 2003 for the top MS drugs, i.e., Rebif, Avonex, Betaseron, and Copaxone, was about $1.7 billion. However, within a six-month period, 6–10% of the patients have to discontinue interferon therapy. These patients are likely to switch to new therapies as they become available. Thus, this is the patient population that will benefit from the compositions discovered at the NIH, i.e., MP4 therapy.

Patent Estate

This technology consists of the following patents and patent applications:

1. U.S. Patent No. 6,083,503, entitled ''Interleukin-2 stimulated T lymphocyte cell death for the treatment of autoimmune diseases, allergic responses, and graft rejection'' (E–137–1991/0–US–03);

2. U.S. Patent No. 5,989,546, entitled ''Interleukin-2 stimulated T lymphocyte cell death for the treatment of allergic responses'' (E–137–1991/0–US–04);

3. U.S. Patent No. 5,935,575, entitled ''Interleukin-4 stimulated T lymphocyte cell death for the treatment of allergic disorders'' (E–151–1992/0–US–11);

4. U.S. Patent Application No. 08/431,644 entitled ''Modified Myelin Basic Protein Molecules'' (E–033–1996/0–US–01); and

5. U.S. Patent Application No. 08/482,114 entitled ''Modified Proteolipid Protein Molecules'' (E–128–1996/1–US–01).

Next Step: Teleconference

There will be a teleconference where the principal investigator will explain this technology. Licensing and collaborative research opportunities will also be discussed. If you are interested in participating in this teleconference please call or e-mail Mojdeh Bahar; (301) 435–2950; *baharm@mail.nih.gov.* OTT will then e-mail you the date, time and number for the teleconference.

Dated: October 22, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–21104 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel, Developmental Center for Research on Complementary and Alternative Medicine.

Date: November 12–14, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Marriott at Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Martina Schmidt, PhD., Scientific Review Administrator, Office of Scientific Review, National Center for Complementary & Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301–594–3456, *schmidma@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Dated: October 22, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5310 Filed 10–25–07; 8:45 am]

BILLING CODE 4140–01–M