

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); Sjögren'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 methotrexate 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.

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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.

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