Dated: February 7, 2008.

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

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.

Use of Amyloid Proteins as Vaccine Scaffolds

Description of Technology: Amyloid proteins are composed of peptides whose chemical properties are such that they spontaneously aggregate *in vitro* or *in vivo*, assuming parallel or antiparallel beta sheet configurations. Amyloid proteins can arise from peptides which, though differing in primary amino acid sequences, assume the same tertiary and quaternary structures. The amyloid structure presents a regular array of accessible N-termini of the peptide molecules.

Claimed in this application are compositions and methods for use of amyloid proteins as vaccine scaffolds, on which peptide determinants from microorganisms or tumors may be presented to more efficiently generate and produce a sustained neutralizing antibody response to prevent infectious diseases or treat tumors. The inventors have arrayed peptides to be optimally immunogenic on the amyloid protein scaffold by presenting antigen using three different approaches. First, the N-terminal ends of the amyloid forming peptides can be directly modified with the peptide antigen of interest; second, the N-termini of the amyloid forming peptides are modified with a linker to which the peptide antigens of interest are linked; and third, the scaffold amyloid may be modified to create a chimeric molecule.

Aside from stability and enhanced immunogenicity, the major advantages of this approach are the synthetic nature of the vaccine and its low cost. Thus, concerns regarding contamination of vaccines produced from cellular substrates, as are currently employed for some vaccines, are eliminated; the robust stability allows the amyloid based vaccine to be stored at room temperature for prolonged periods of time; and the inexpensive synthetic amino acid starting materials, and their rapid spontaneous aggregation *in vitro* should provide substantial cost savings over the resource and labor-intensive current vaccine production platforms.

Application: Immunization to prevent infectious diseases or treat chronic conditions or cancer.

Developmental Status: Vaccine candidates have been synthesized and preclinical studies have been performed.

Inventors: Amy Rosenberg (CDER/FDA), James E. Keller (CBER/FDA), Robert Tycko (NIDDK).

Patent Status: U.S. Provisional Application No. 60/922,131 filed 06 Apr 2007 (HHS Reference No. E–106–2007/0–US–01).

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

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

Collaborative Research Opportunity: The FDA, Division of Therapeutic Proteins (CDER) and Office of Vaccines, Division of Bacterial Products (CBER) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize amyloid based vaccines for prevention of infectious disease or treatment of malignant states. Please contact Amy Rosenberg at *amy.rosenberg@fda.hhs.gov* or (301) 827–1794 for more information.

Inhibiting HIV Infection Using Integrin Antagonists

Description of Technology: Infection with HIV depletes and impairs CD4 cells, a key component of the immune system. Effective therapies such as highly active antiretroviral therapy (HAART) have focused on preserving CD4 cells. However, long term HAART has significant toxicity associated with it. The current technology describes the use of integrin antagonists as an alternative to treating or preventing HIV infection and replication. Specifically, α4 integrin plays a role in directing lymphocytes to the primary site of HIV replication. Inhibition of the interaction of α4β1 or α4β7 with gp120 can therefore be important in the development of effective HIV treatments.

Applications: Inhibiting HIV infection; Inhibiting HIV replication.

Development Status: In vitro data.

Inventors: James Arthos, Diana Goode, Claudia Cicala, and Anthony Fauci (NIAID).

Patent Status:

U.S. Patent Application No. 60/873,884 filed 07 Dec 2006 (HHS Reference No. E–055–2007/0–US–01)

U.S. Patent Application No. 60/920,880 filed 03 Mar 2007 (HHS Reference No. E–055–2007/1–US–01)

U.S. Patent Application No. 60/957,140 filed 21 Aug 2007 (HHS Reference No. E–055–2007/2–US–01)

PCT Patent Application No. PCT/US2007/086663 filed 06 Dec 2007 (HHS Reference No. E–055–2007/3–PCT–01)

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

Licensing Contact: Susan Ano, PhD; 301–435–5515; *anos@mail.nih.gov*.

Collaborative Research Opportunity: The NIAID Laboratory of Immunoregulation is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Dr. James Arthos at 301–435–2374 for more information.

Coacervate Microparticles Useful for the Sustained Release Administration of Therapeutics Agents

Description of Technology: The described technology is a biodegradable microbead or microparticle, useful for the sustained localized delivery of biologically active proteins or other molecules of pharmaceutical interest. The microbeads are produced from several USP grade materials, a cationic polymer, an anionic polymer and a binding component (e.g., gelatin, chondroitin sulfate and avidin), in predetermined ratios. Biologically active proteins are incorporated into preformed microbeads via an introduced binding moiety under nondenaturing conditions.

Proteins or other biologically active molecules are easily denatured, and once introduced into the body, rapidly cleared. These problems are circumvented by first incorporating the protein into the microbead. Microbeads with protein payloads are then introduced into the tissue of interest, where the microbeads remain while degrading into biologically innocuous materials while delivering the protein/drug payload for adjustable periods of time ranging from hours to weeks. This technology is an improvement of the microbead technology described in U.S. Patent No. 5,759,582.

Applications: This technology has two commercial applications. The first is a pharmaceutical drug delivery application. The bead allows the incorporated protein or drug to be delivered locally at high concentration, ensuring that therapeutic levels are reached at the target site while reducing side effects by keeping systemic concentration low. The microbead accomplishes this while protecting the biologically active protein from harsh conditions traditionally encountered during microbead formation/drug formulation.

The microbeads are inert, biodegradable, and allow a sustained release or multiple-release profile of treatment with various active agents without major side effects. In addition, the bead maintains functionality under physiological conditions.

Second, the microbeads and microparticles can be used in various research assays, such as isolation and separation assays, to bind target proteins from biological samples. A disadvantage of the conventional methods is that the proteins become denatured. The denaturation results in incorrect binding studies or inappropriate binding complexes being formed. The instant technology corrects this disadvantage by using a bead created in a more neutral pH environment. It is this same environment that is used for the binding of the protein of interest as well.

Inventor: Phillip F. Heller (NIA).

Patent Status:

U.S. Provisional Application No. 60/602,651 filed 19 Aug 2004 (HHS Reference No. E–116–2004/0–US–01)

PCT Application No. PCT/US2005/026257 filed 25 Jul 2005, which published as WO 2006/023207 on 02 Mar 2006 (HHS Reference No. E–116–2004/0–PCT–02)

U.S. Patent Application No. 11/659,976 filed 12 Feb 2007 (HHS Reference No. E–116–2004/0–US–03)

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

Licensing Contact: Susan O. Ano, PhD; 301/435–5515; *anos@mail.nih.gov*.

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New Inhibitors of Multidrug Resistant Proteins Such as ABCG2

Description of Technology: Drug resistance plays a significant role in the failure of cancer chemotherapy. Some proteins such as ABCG2, Pgp and MRP1 that belong to the superfamily of ATP-binding cassette transporters contribute to this process.

Two categories of ABCG2 protein inhibitors—botryllamides, isolated from a marine sponge, and naphthopyrones, isolated from marine sea stars—have been obtained by high-throughput screening of 89,000 natural product extracts from the Natural Products Repository at NCI.

These new compounds serve as potential therapeutic agents for cancer chemotherapy either exclusively or in combination with conventional regimens. The study of structure-activity relationships will help delineate features that would enhance activity and specificity to multiple drug resistant proteins.

Advantages: Increase bioavailability of orally administered drugs; Enhance drug delivery to certain tissues.

Applications: Cancer therapeutics; Cancer stem cell research; Study of structure, function and relevance of MDR in cancer.

Market: Cancer is the second leading cause of death in America, after heart disease. Multiple drug resistance is a significant impediment in the treatment of cancers resulting in poor prognosis. Some cancers with demonstrated high levels of MDR are leukemia, colon, renal, liver, adrenocortical, and pancreatic. Breast, ovarian, sarcoma and small-cell lung cancer show increased MDR on treatment.

This new technology has the potential to increase the effectiveness of conventional chemotherapy and prognosis of cancer.

Developmental Status: Early stage.

Inventors: Curtis J. Henrich *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 60/018,758 filed 03 Jan 2008 (HHS Reference No. E–315–2007/0–US–01).

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: John Stansberry, PhD; 301/435–5236; *stansbej@mail.nih.gov*.

TGF-β Gene Expression Signature in Cancer Prognosis

Description of Technology: Hepatocellular carcinoma (HCC) is the third leading cause of cancer death worldwide, and it is very heterogeneous in terms of its clinical presentation as well as genomic and transcriptomic patterns. This heterogeneity and the lack of appropriate biomarkers have hampered patient prognosis and treatment stratification.

Available for licensing is a novel temporal TGF-β gene expression signature that predicts HCC patient clinical outcomes. Patients with tumors expressing late TGF-β responsive genes had a malignant prognosis and an invasive tumor phenotype as evaluated by decreased survival time, increased tumor recurrence, and vascular invasion rate. Additionally, this signature may also be able to prognose other cancers, including lung cancer.

Applications: Method to diagnose cancer; Method to monitor cancer progression and aid clinicians to choose appropriate therapies; Commercial kits to prognose cancer.