Public Teleconference Regarding Licensing and Collaborative Research Opportunities for: A Promising Treatment for Inflammatory Arthritis Targeting the Pre-ligand Assembly Domain (PLAD) of Tumor Necrosis Factor Receptors; Michael J. Lenardo et al. (NIAD)

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

ACTION: Notice.

Technology Summary
The technology is an innovative treatment for inflammatory arthritis that involves modulating Tumor Necrosis Factor Receptor (TNFR) 1 signaling. NIH scientists have discovered that the Pre-ligand Assembly Domains (PLADs) of TNFR1 can be selectively blocked by soluble P60-PLAD protein compositions (P60 PLAD-Sol) which interfere with TNFR1 assembly thereby preventing the inflammatory effects of TNFα both in vitro and in vivo.

Technology Description
Current anti-TNFα arthritis treatments rely on the use of antibodies or fusion proteins directed against TNFα to reduce inflammation. The cytokine TNFα plays a key role in the pathogenesis of numerous autoimmune and inflammatory diseases including psoriatic, rheumatoid, and septic arthritis. It has been shown that blocking TNFα has a dramatic therapeutic effect; however, blocking TNFα also blocks TNFα’s beneficial effects during immune responses that are mediated through TNFR2.

This invention involves a functional domain, which is essential for signaling involving receptors of the TNFR superfamily including TNFR-1 (p60), TNFR-2 (p80), FAS, TRAIL-R, LTR, CD40, CD30, CD27, HVEM, OX40 and DR4. PLADs can be isolated as functional polypeptides which can be useful in inhibiting the first step in TNFR mediated signaling, ligand-independent assembly of members of the TNFR superfamily. The ability to inhibit TNFR signaling suggests that these PLAD polypeptides may be useful in developing new therapeutic molecules or as therapeutic molecules themselves.

P60 PLAD-Sol has the benefit of selectively blocking only the signaling of TNFR1, not signaling mediated through TNFR2. Treatment of mice with the P60 PLAD-Sol ameliorated inflammatory joint disease with no side effects in 5 different animal models of arthritis including: collagen-induced arthritis, adjuvant and lipopolysaccharide induced arthritis, and joint disease due to TNF. Therefore, P60 PLAD-Sol may lead to novel inflammatory arthritis treatments that avoid the serious side effects associated with currently marketed therapeutics that directly block TNFα rather than TNFR1.

Competitive Advantage of Our Technology
More than 20% of the population in the USA currently seek arthritis treatment; of these over 2 million suffer rheumatic symptoms. Worldwide this figure is close to five million people. Existing commercially available anti-TNFα treatments are expensive: in the U.S. Enbrel® (Remicade®), and Humira® all cost more than $10,000 per year. In addition to this market there is the potential to treat other inflammatory based diseases such as Crohn’s Disease and Multiple Sclerosis. Owing to the high price of these agents and their increased use in treatment, the market for TNFα inhibitors is expected to grow from $7.1 billion in 2005 to nearly $12 billion in 2014 in the United States, Western Europe, and Japan.

The existing TNF blockers, e.g., Enbrel® (Etanercept—a dimeric fusion protein by Amgen/Wyeth), Remicade® (Infliximab—a mouse chimeric anti-TNF monoclonal antibody by J&J), and Humira® (Adalimumab—a humanized anti-TNF monoclonal antibody by Abbott) have been effective in the treatment of rheumatoid arthritis. They are beneficial in over 70% of patients including many who have not responded to Rheumatrex® (Methotrexate—an antimetabolite by STADA); however, serious and sometimes fatal side effects have been observed. In addition, the current costs of these drugs are prohibitive for many patients. This technology has the potential to be less expensive yet more effective than existing products.

For arthritis sufferers who are unresponsive to, or adversely affected by, current inflammatory arthritis treatments our technology is a new method of blocking inflammation that provides a more targeted action. Unlike the currently marketed anti-TNF medications, P60 PLAD-Sol has the potential to more effectively treat a broader range of inflammatory diseases with no known side-effects. The current anti-TNF drugs directly block the binding of TNFα to both TNFR1 and TNFR2. There is evidence that this inhibits the beneficial effects mediated by TNFR2, while arresting the disease-causing effects of TNFR1. This is because the P60 PLAD-Sol involves the use of small soluble proteins that preferentially target only the PLAD of TNFR1. In our models, a dose of a P60 PLAD-Sol (5 mg/kg) had similar effects to doses of Infliximab (10 mg/kg) and Etanercept (0.4 mg/kg) that have been used clinically in the amelioration of arthritis. As a selective TNFR1 blocking agent, this technology may avoid the serious side effects of these currently available compounds yet have enhanced efficacy.

Patent Estate
A PCT application, filed 9 February 2001 (WO 01/58953), has entered the national phase in the US, EP, AU and CA.

Next Step: Teleconference
There will be a teleconference where the principal investigator will discuss non-confidential information concerning this technology. Licensing and collaborative research opportunities will also be discussed. If you are interested in participating in this teleconference please call or email Mojdeh Bahar; (301) 435–2950; baharm@mail.nih.gov. OTT will then email you the date, time and number for the teleconference.

Dated: October 2, 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

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The
Mandatory Guidelines were first published in the Federal Register on April 11, 1988 (53 FR 11970), and subsequently revised in the Federal Register on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the Federal Register during the first week of each month. If any laboratory’s certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, until such time as it is restored to full validity tests on urine specimens:

- ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016, (Formerly: Bayshore Clinical Laboratory)
- ACM Medical Laboratory, Inc., 160 Elm Grove Park, Rochester, NY 14624, 585–429–2264
- Baptist Medical Center-Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)
- Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917
- Diagnostic Services, Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 239–561–8200/800–735–5416
- Doctors Laboratory, Inc., 2906 Julia Hill Ave., Nashville, TN 37210, 615–288–2281
- DrugScan, Inc., P.O. Box 2969, 1119 Meams Road, Warminster, PA 18974, 215–674–9310
- Elsolyh Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609
- General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6225
- Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretta, LA 70053, 504–361–8989/800–433–3823, (Formerly: Laboratory Specialists, Inc.)
- Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387
- Laboratory Corporation of America Holdings, 69 First Ave., Ranitan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.)
- Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900 / 800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompucChem Laboratories, Inc., a subsidiary of Roche Biomedical Laboratory; Roche Compuchem Laboratories, Inc., a member of the Roche Group)
- Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042 / 800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)
- LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Leesia, KS 66219, 913–808–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)
- Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715–389–3734/800–331–3734
- MAXXAM Analytics Inc.*, 6740 Campbello Pkwy, Mississauga, ON Canada, L5N 2L8, 905–817–6000, (Formerly: NOVAMANN (Ontario), Inc.)
- MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295
- Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, Mn 55417, 612–725–2088
- National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515
- One Source Toxicology Laboratory, Inc., 1213 Genoa Red Bluff Pasadena, TX 77504 887–747–3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)
- Oregon Medical Laboratories 123 International Way, Springfield, OR 97477 541–341–8092
- Pacific Toxicology Laboratories 9348 DeSoto Ave. Chatsworth, CA 91311 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)
DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Designation of Manager, National Communications System

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice.

SUMMARY: The Secretary of Homeland Security announces the designation of the Under Secretary for Preparedness, Directorate for Preparedness, as the Manager, National Communications System (NCS).

DATES: The designation of the Manager, National Communications System, is effective August 15, 2006.

FOR FURTHER INFORMATION CONTACT: Ms. Marilyn Witcher, Chief, Industry, Government, and External Affairs, National Communications System, telephone (703) 235–5515, e-mail: Marilyn.Witcher@dhs.gov or write the Deputy Manager, National Communications System, PREP/CS/T/NCS/N5, Mail Stop 8500, Department of Homeland Security, 245 Murray Lane, Building 410, Washington, DC 20528–8500.

SUPPLEMENTARY INFORMATION: This designation is issued in accordance with section 1(e)(1) of Executive Order 12472 of April 3, 1984, as amended by section 46 of Executive Order 13286 of February 28, 2003. It supersedes the designation to the Assistant Secretary of Homeland Security for Infrastructure Protection.

The NCS consists of the telecommunications assets of the entities represented on the NCS Committee of Principals and an administrative structure consisting of the Executive Agent, the NCS Committee of Principals, and the Manager. The mission of the NCS is to assist the President, the National Security Council, the Homeland Security Council, the Director of the Office of Science and Technology Policy, and the Director of the Office of Management and Budget in:

(1) The exercise of designated telecommunications functions and responsibilities; and

(2) The coordination of the planning for and provision of national security and emergency preparedness communications for the Federal Government under all circumstances, including crisis or emergency, attack, recovery, and reconstitution.

As stated in Section 1(g) of Executive Order 12472 of April 3, 1984, as amended, the Manager, NCS, shall develop for consideration by the NCS Committee of Principals and the Executive Agent:

(1) A recommended evolutionary telecommunications architecture designed to meet current and future Federal Government national security and emergency preparedness telecommunications requirements; and

(2) Plans and procedures for the management, allocation, and use,