DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

[HHS Reference Nos. E–095–2000/0, 1, 2, 3 and 4]

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. (NIAID)

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 e-mail 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.

[FR Doc. E6–16735 Filed 10–10–06; 8:45 am]

BILLING CODE 4140–01–P

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, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Mandatory Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen 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 Elmgrove Park, Rochester, NY 14624, 585–429–2264

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400

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 Drive, Valdosta, GA 31602, 229–671–2281

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215–674–9310

Dynacare Kasper Medical Laboratories*, 10150–102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780–451–3702 / 800–661–9876

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Gamma-Dynacare Medical Laboratories*, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6225

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Laboratory Specialists, Inc.)

Kroll Scientific Testing Laboratories, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130, (Formerly: Scientific Testing Laboratories, 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., Raritan, 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., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 10788 Roselle St., San Diego, CA 92121, 800–882–7272, (Formerly: Poisonlab, Inc.)

Laboratory Corporation of America Holdings, 550 17th Ave., Suite 300, Seattle, WA 98122, 206–923–7020/800–898–0180, (Formerly: DrugProof, Division of Dynacare/Laboratory of Pathology, LLC; Laboratory of Pathology of Seattle, Inc.; DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)

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., Lenexa, KS 66219, 913–888–3927/800–873–8845, (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 Campobello Road, Mississauga, ON Canada L5N 2L8, 905–817–5700, (Formerly: NOVAMANN (Ontario), Inc.)

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

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 888–747–3774 (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)

Pathology Associates Medical Laboratories 110 West Cliff Dr. Spokane, WA 99204 509–755–8991 / 800–541–7897 x7
Physicians Reference Laboratory 7800 West 110th St. Overland Park, KS 66210 913–339–0372 / 800–821–3627
Quest Diagnostics Incorporated 3175 Presidential Dr. Atlanta, GA 30340 770–452–1590 / 800–729–6432 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)
Quest Diagnostics Incorporated 4770 Regent Blvd. Irving, TX 75063 800–824–6152 (Moved from the Dallas location on 03/31/01; Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)
Quest Diagnostics Incorporated 4230 South Burnham Ave., Suite 250 Las Vegas, NV 89119–5412 702–733–7866 / 800–433–2750 (Formerly: Associated Pathologists Laboratories, Inc.)
Quest Diagnostics Incorporated 400 Egypt Road Norristown, PA 19403 610–631–4600 / 877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)
Quest Diagnostics Incorporated 506 E. State Pkwy. Schaumburg, IL 60173 800–669–6995 / 847–885–2010 (Formerly: SmithKline Beecham Clinical Laboratories; International Toxicology Laboratories)
Quest Diagnostics Incorporated 7600 Tyrone Ave. Van Nuys, CA 91405 866–370–6699 / 818–989–2521 (Formerly: SmithKline Beecham Clinical Laboratories)
Quest Diagnostics Incorporated 2282 South Presidents Drive, Suite C West Valley City, UT 84120 801–606–6301 / 800–322–3361 (Formerly: Northwest Toxicology, a LabOne Company; LabOne, Inc., dba Northwest Toxicology; NWT Drug Testing, NorthWest Toxicology, Inc.; Northwest Drug Testing, a division of NWT Inc.)
S.E.D. Medical Laboratories 5601 Office Blvd. Albuquerque, NM 87109 505–727–6300 / 800–999–5227
South Bend Medical Foundation, Inc. 530 N. Lafayette Blvd. South Bend, IN 46601 574–234–4176 x276
Southwest Laboratories 4645 E. Cotton Center Boulevard Suite 177 Phoenix, AZ 85040 602–438–8507 / 800–279–0027
Sparrow Health System Toxicology Testing Center, St. Lawrence Campus 1210 W. Saginaw Lansing, MI 48915 517–364–7400 (Formerly: St. Lawrence Hospital & Healthcare System)
St. Anthony Hospital Toxicology Laboratory 1000 N. Lee St. Oklahoma City, OK 73101 405–272–7052
Toxicology & Drug Monitoring Laboratory University of Missouri Hospital & Clinics 301 Business Loop 70 West, Suite 208 Columbia, MO 65203 573–882–1273
Toxicology Testing Service, Inc. 5426 N.W. 79th Ave. Miami, FL 33166 305–593–2260
US Army Forensic Toxicology Drug Testing Laboratory 2490 Wilson St. Fort George G. Meade, MD 20755–5235 301–677–7085

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 13, 2004 (69 FR 19644). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Dated: October 4, 2006.

Elaine Parry,

Acting Director, Office Program Services, SAMHSA.

[FR Doc. E6–16744 Filed 10–10–06; 8:45 am]

BILLING CODE 4160–20–P

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;

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