

before June 3, 2008 for priority consideration.

Interested CRADA collaborators must submit a confidential proposal summary to the NIAID (attention Percy S. Pan at the address mentioned below) on or before June 3, 2008 for consideration. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest. CRADA and PHS License Applications submitted thereafter may be considered if a suitable CRADA collaborator or Licensee(s) has not been selected.

**ADDRESSES:** Questions about licensing opportunities should be addressed to Peter Soukas, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, Telephone: (301) 435-4646 ; Facsimile: (301) 402-0220; E-mail: [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov). Information about Patent Applications and pertinent information not yet publicly described can be obtained under the terms of a Confidential Disclosure Agreement. Respondents interested in licensing the invention will be required to submit an "Application for License to Public Health Service Inventions."

Depending upon the mutual interests of the Licensee(s) and the NIAID, a CRADA to collaborate to develop WNV vaccines in humans may also be negotiated. Proposals and questions about this CRADA opportunity should be addressed to Percy S. Pan, Technology Development Associate, Office of Technology Development, NIAID, 6610 Rockledge Drive, Room 4071, Bethesda, MD 20892-6606, Telephone: (301) 451-3523; E-mail: [panp@niaid.nih.gov](mailto:panp@niaid.nih.gov). Respondents interested in submitting a CRADA Proposal should be aware that it may be necessary to secure a license to the above-mentioned patent rights in order to commercialize products arising from a CRADA.

**SUPPLEMENTARY INFORMATION:** WNV has recently emerged in the U.S. and is considered a significant emerging disease that has embedded itself over a considerable region of the U.S. WNV infections have been recorded in humans as well as in different animals. To date, WNV has killed 294 people in the U.S. and caused severe disease in more than 4222 others. This project is part of NIAID's comprehensive emerging infectious disease program, which supports research on bacterial,

viral, and other types of disease-causing microbes.

The methods and compositions of this invention provide a means for prevention of WNV infection by immunization with attenuated, immunogenic viral vaccines against WNV. The invention involves a chimeric virus form consisting of parts of WNV and Dengue virus. Construction of the hybrids and their properties are described in detail in PNAS, Pletnev AG et al., 2002; 99(5):3036-3041.

The WNV chimeric vaccine does not target the central nervous system, which would be the case in an infection with wild type WNV. The vaccine stimulates strong anti-WNV immune responses, even following a single dose of the vaccine. When injected into mice, the vaccine protected all of the immunized animals from subsequent exposure to the New York WNV strain. The vaccine was also effective in primates. Researchers intend to begin human trials in late 2003.

The WNV vaccine may be used to protect the human population, particularly the elderly people, and domestic animals from WNV infection in the affected regions of the U.S. as well as worldwide.

The invention claimed in HHS Reference No. E-357-2001/1-US-02, "Construction of West Nile Virus and Dengue Virus Chimeras for Use in a Live Virus Vaccine to Prevent Disease Caused by West Nile Virus" AG Pletnev et al.), U.S. Patent Application No. 10/871,775, filed June 18, 2004, is available for exclusive or non-exclusive licensing for developing a vaccine against WNV for humans or veterinary use in accordance with 35 U.S.C. 207 and 37 CFR Part 404. NIAID is also interested in further development of the technology under one or more CRADAs in the human applications described below.

Under the CRADA the production of WNV vaccines for humans will be optimized and the vaccine evaluated in a series of clinical studies in humans as well as initial safety testing in humans. Positive outcomes of these studies will indicate continued clinical development aimed at supporting regulatory approval of a product to be labeled for use in humans. The Public Health Service (PHS) has filed patent applications both in the U.S. and internationally related to this technology. Notice of the availability of the patent application for licensing was first published in the **Federal Register** on May 2, 2002 (67 FR 22093).

NIAID's principal investigator has extensive experience with live attenuated vaccines, their production

and testing, and clinical trials. The Collaborator in this endeavor is expected to assist NIAID in evaluating its current system for producing the WNV chimeras claimed in the patent applications and to develop and optimize an alternative production method, if necessary, to manufacture sufficient quantities of the vaccine for clinical testing in humans and initial safety studies in humans. The Collaborator must have experience in the manufacture of live attenuated vaccines according to applicable FDA guidelines and Points to Consider documents to include Good Manufacturing Procedures (GMP). In addition, it is expected that the Collaborator would provide funds to supplement the LID's research budget for the project and to support the initial human testing.

The capability statement should include detailed descriptions of: (1) Collaborator's expertise in the production of live attenuated vaccines, (2) Collaborator's ability to manufacture sufficient quantities of the vaccine according to FDA guidelines and Points to Consider documents, (3) the technical expertise of the Collaborator's principal investigator and laboratory group in preclinical safety testing (e.g., expertise in *in vitro* and *in vivo* toxicity and pharmacology studies) and initial human safety studies, and (4) Collaborator's ability to provide adequate funding to support initial human safety studies required for marketing approval.

Dated: February 25, 2008.

**Michael Mowatt,**

*Director, Office of Technology Development, National Institute of Allergy and Infectious Diseases, National Institutes of Health.*

Dated: February 26, 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**

#### **Prospective Grant of Exclusive License: The Development of Human Therapeutics for the Treatment of Cancer**

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

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Patent 5,167,956 entitled "Immunotoxin with in-vivo T-Cell suppressant activity and Methods of Use" [HHS Ref. E-012-1991/0-US-01], U.S. Patent Application 60/037,196 entitled "Novel Vectors and Expression Methods for Producing Mutant Proteins" [HHS Ref. E-043-1997/0-US-01], U.S. Patent Application 60/039,987 entitled "Novel Immunotoxins and Methods of Inducing Immune Tolerance" [HHS Ref. E-044-1997/0-US-01], U.S. Patent Application 09/064,413 entitled "Use of Immunotoxins to Induce Immune Tolerance to Pancreatic Islet Transplantation" [HHS Ref. E-059-1998/0-US-01], U.S. Patent Application 09/291,712 entitled "Methods Related to the Combined Use of Immunotoxins and Agents that Inhibit Dendritic Cell Maturation" [HHS Ref. E-168-1999/0-US-01], and all continuing applications and foreign counterparts, to CK Life Sciences International, Inc., which has offices in Hong Kong. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to: The production and use of the immunotoxins covered by the licensed patent rights for the treatment of T-cell mediated diseases, including but not limited to T-cell lymphoma and autoimmune diseases.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before May 5, 2008 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; E-mail: [lambertson@od.nih.gov](mailto:lambertson@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** The invention concerns immunotoxins and methods of using the immunotoxins for the treatment of autoimmune diseases and T cell malignancies. A specific immunotoxin covered by this

technology is A-dmDT390-bisFV (UCHT1). The immunotoxins are targeted via an antibody that is specific to T cells, allowing the specific ablation of both malignant T cells and resting T cells. The transient ablation of resting T cells can "reset" the immune system by accentuating tolerating responses to autoimmune diseases like Lupus. Additionally, the immunotoxins can be used to treat T cell related cancers such as non-Hodgkins' lymphomas, including cutaneous T cell lymphoma (CTCL).

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February 27, 2008.

**Bonny Harbinger,**

*Deputy Director, 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, and will be omitted from the monthly listing thereafter.

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

**FOR FURTHER INFORMATION CONTACT:** Mrs. Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 2-1042, One 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).