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Dated: September 15, 2006.

Robert G. McSwain,

Deputy Director, Indian Health Service.

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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.

An HIV Protein for Use as a Novel Therapeutic or Vaccine Component

Description of Technology: Latent HIV presents a challenge for complete removal of the virus in infected individuals and is becoming an increasingly important consideration in the identification of potential HIV therapeutics or treatment regimens. These transcriptionally inactive HIV reservoirs lay dormant in a portion of infected cells and are capable of evading both host defenses and existing antiretroviral therapy. The present technology offers a potential solution for complete eradication of HIV in infected individuals.

This technology describes immunogenic and therapeutic compositions related to HIV p28^{TEV} protein, first protein expressed during HIV infection in the case of the pHXB2 isolate. p28^{TEV} functions in the regulation of HIV transcription and may be important for the expression of latent virus. A number of p28^{TEV} associated compositions are available for licensing and commercial development including: (1) The p28^{TEV} polypeptide from one or more HIV clades, (2) nucleic acids encoding these p28^{TEV} polypeptides, (3) a polypeptide with significant sequence homology to p28^{TEV}, and (4) immunogenic fragments of these polypeptides. Additional compositions include antibodies and antagonists that act to inhibit p28^{TEV} activity. Adjuvants, immunomodulators and compounds used in combination with p28^{TEV} for the treatment of HIV infection are also included in the available technology.

Applications: (1) Novel therapeutics for treatment of HIV infection; (2) Novel HIV vaccine component.

Development Status: Preclinical data are available at this time.

Inventors: Genoveffa Franchini et al. (NCI)

Patent Status: U.S. Patent Application No. 11/364,873 filed 27 Feb 2006 (HHS Reference No. E-072-2004/3-US-01)

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

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

Collaborative Research Opportunities: The National Cancer Institute Vaccine Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Methods of Targeting the Establishment of the HIV Viral Reservoir. Please contact Betty Tong, PhD at 301-594-4263 or tongb@mail.nih.gov for more information.

Swine Hepatitis E Virus Available for Use in Diagnosis, Prevention and Treatment of Hepatitis E

Description of Technology: Hepatitis E virus (HEV) is the cause of Hepatitis E, a liver disease that occurs primarily in developing countries due to fecal contaminated drinking water. Outbreaks of HEV infection have caused epidemics in Africa, Central and Southeast Asia and Mexico and cases of the disease have also been reported sporadically in more developed countries. Hepatitis E is most often overcome by a host's natural defenses; however the disease is more severe in pregnant women, who exhibit a 20% mortality rate due to HEV infection. Presently, no vaccines or

therapeutic agents, which prevent or treat HEV infection, are commercially provided.

An isolated strain of swine HEV is currently available for licensing and commercial development. The nucleotide and amino acid sequences of the available virus are significantly homologous to human HEV and antibodies induced by the agent were shown to cross react with a human HEV antigen. The present technology provides a mechanism for augmenting the immune response against HEV in infected individuals and is thus useful for the development of novel vaccines and therapeutics for prevention and treatment of HEV infection in humans. In addition, the available viral strain may be used to develop diagnostic tools for efficient detection of HEV contamination of food and water in developing countries, especially in regions of Africa, Asia and Mexico, where HEV is endemic.

Applications: (1) Development of diagnostic tools for identification and detection of HEV infection; (2) HEV vaccination in developing countries, where individuals are at higher risk for infection; (3) Research and development of anti-HEV therapeutics agents.

Development Status: Preclinical data are available at this time.

Inventors: Xiang-jin Meng, Robert H. Purcell, Suzanne U. Emerson (NIAID)

Patent Status: U.S. Patent No. 6,432,408 issued 13 Aug 2002 (HHS Reference No. E-203-1997/0-US-04) and European Patent Application No. 98934568 filed 17 Jul 1998 (HHS Reference No. E-203-1997/0-EP-03)

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

Licensing Contact: Chekesha Clingman, PhD; 301/435-5018; clingmac@mail.nih.gov.

Collaborative Research Opportunity: The NIAID Laboratory of Infectious Diseases, Hepatitis Viruses Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize swine HEV or its products. Please contact Robert H. Purcell at rpurcell@niaid.nih.gov for more information.

Dated: September 18, 2006.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

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