DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is 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 any 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.

Human UGRP1 (Uteroglobin-Related Protein 1) Promoter and Its Use

Shioko Kimura and Tomoaki Nimi (NCI). PCT Application No. PCT/US02/19456 filed 18 Jun 2002 (with priority to 20 Jun 2001), which published as W0 03/000111 on 03 Jan 2003 (DHHS Reference No. E–058–2001/0–PCT–02). Licensing Contact: Susan Carson; (301) 435–5020; carsonsu@mail.nih.gov.

Asthma is a genetically complex, multi-factorial disease affecting more than 17 million people in the United States alone and costing approximately US$6 billion to treat annually. Identification, mapping and linkage analyses of Single Nucleotide Polymorphisms (SNPs) have been increasingly used both to study the genetic etiology of asthma and to detect genetic loci contributing to asthma susceptibility. Researchers from the National Cancer Institute have described a novel gene, located in an asthma-susceptibility gene loci 5q31–34, named UGRP1 (uteroglobin-related protein 1) and an associated polymorphism that is significantly associated with asthma (Nimi *et al.* (2002) Am. J. Hum. Genet 70: 718–725).

UGRP1 is a homodimeric secretory protein of ~10 kDA and is expressed only in lung and trachea. The –112G/A polymorphism was identified in the human UGRP1 gene promoter and is responsible for a 24% reduction in the promoter activity in relation to the –112G allele, as examined by transfection analysis. In a case-control study using 169 Japanese individuals (84 with asthma and 85 unrelated healthy controls) those with a –112A allele (G/A or A/A) were 4.1 times more likely to have asthma than were those with the wild-type allele(G/G).

The invention describes the –112G/A polymorphism and the UGRP1 promoter region as well as methods for detecting polymorphisms present in the UGRP1 promoter which can be used as indicators for diagnosing or for predicting a predisposition to develop a respiratory disorder. The complex and polygenic nature of asthma suggests that this potential asthma susceptibility allele can be of great value not only to companies targeting respiratory diseases such as asthma but also to those more broadly involved in gene discovery, gene mapping, association-based candidate polymorphism testing, pharmacogenetics, diagnostics and risk profiling.

Dated: December 1, 2003.

Steven M. Ferguson,

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

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Construction of Replication-Competent Chimeric Simian Immunodeficiency Virus (SIV) Human Immunodeficiency Virus Type 1 (HIV–1) Viruses that Replicate Using HIV–1 Reverse Transcriptase and Integrase (IN): A Model System for Development and Testing of Antiviral Agents for the Treatment of HIV–1 Infection

Vijay K. Pathak and Yijun Zhang (NCI). DHHS Reference No. E–019–2004/0—Research Tool. Licensing Contact: Michael Ambrose; (301) 594–6565; *ambrosea@mail.nih.gov.*

Currently antiviral therapy is based on a cocktail that inhibits viral replication. These drugs are targeted toward the Reverse Transcriptase (RT) enzyme to inhibit such replication. However, development of HIV drug resistance to these current therapies is the leading blockage to successful treatment of such patients, and as such, leads to the progression of AIDS and eventual death. The goal of developing successful next generation drugs for HIV must contend with (1) the alarming rate of mutation of HIV and (2) an animal model that represents the natural disease in humans. This latter point must also have as one of its properties; the natural occurring mutation and resistance to the therapy in develop.

To address these questions, a chimeric virus was developed between SIV and HIV. The SIV backbone is altered such that the HIV RT and Integrase (IN) enzymes are expressed in infected cells. This allows the use of the macaque as the animal model and having the RT and IN of HIV as the potential drug targets. In this system, novel therapies can be developed and studied in vivo, in single or in combination form, in a manner more similar to the human HIV infection then is currently available. Further, toxicity studies can be designed and results obtained that are more relevant to the human disease condition.

One other advantage is the ability to use the macaque model to discover additional generations of HIV therapies and tested in the same system. This provides identical biological backgrounds to address toxicity concerns of changing medications as one becomes resistant and newer therapies are administered.