further stipulates that in developing and prioritizing the list, the NIH shall consider for each drug on the list: (1) The availability of information concerning the safe and effective use of the drug in the pediatric population; (2) whether additional information is needed; (3) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and (4) whether reformulation of the drug is necessary. For this year, we are providing an update and a summary of the progress made by the prioritization working group from last year's notice until now, as well as a summary of the annual scientific prioritization meeting held with pediatric experts on December 5–6, 2006.

We have updated the complete list of drugs, listed previously in the April 2006 **Federal Register** notice, and post it on the BPCA Web site *http://bpca.nichd.nih.gov/index.cfm.* We will continue to reevaluate this list throughout the year and will provide updates as required, based upon the reauthorization of the BPCA.

In 2005, and with the suggestion of pediatric experts, NIH changed the listing system from a focus on individual off-patent drugs to a therapeutic class-based approach. Pediatric experts indicated that this approach will allow us to compare drugs within a therapeutic class (on and off patent) and give a broader description of the use of these drugs in children. This approach will also allow us to obtain focused expertise in therapeutic areas that will subsequently give us more insight into scientific gaps in treatments of the proposed conditions, as well as feasibility and study designs. Based on expert opinion obtained throughout the year as part of our regular outreach program, a preliminary list of conditions and suggested drugs was drafted and categorized for the 2007 prioritization based on this approach.

The following are the conditions and the drugs discussed in our December 5–6, 2006 scientific meeting with experts in pediatric research: Infectious Diseases, with a focus on Methicillin-resistant Staphylococcus aureus (MRSA) infections; Pediatric Cancer, specifically Neuroblastoma; Neonatal Pain; and Asthma. The gaps in scientific knowledge as well as specific drugs thought to be effective for treatment in each of these conditions were then discussed based on off-patent status, gaps in pediatric labeling, and the potential for providing a health benefit in the general pediatric population. We also provided updates on our current work in the areas of Pediatric Hypertension, Sickle Cell Anemia, and Attention Deficit Hyperactivity Disorder during this meeting. There was also a brief discussion on future areas of consideration, pending the reauthorization of the BPCA, that include topics such as childhood obesity, counter-terrorism research, and Fragile X Syndrome.

Following below are the conditions and drugs we discussed in the December 5–6, 2006, scientific meeting with experts in pediatric research. We will add these conditions and drugs, and their indications for use, to the Priority List for 2007 for which pediatric studies are most urgently needed.

Treatment of Pediatric Cancers: 13-Cis-Retinoic Acid

There is a need for information regarding the pharmacokinetics, safety, and efficacy of 13-Cis-Retinoic Acid in the treatment of neuroblastoma.

Treatment of Pediatric MRSA: Clindamycin, Tetracycline, Doxycycline and Trimethoprim-Sulfamethoxazole

There is a need for further pharmacokinetic and safety data in the use of these drugs to treat children with MRSA infections.

In addition to the above conditions and their associated drugs for consideration, the following are conditions that have been identified as needing improvements in the treatment strategies and/or assessments in pediatrics.

Pediatric Hypertension

Data from the medical literature, clinical trials, and experience were presented and discussed by experts in the field of Pediatric Hypertension. Gaps in knowledge in this field include standardization of blood pressure measurements in children as well as the sequence of drugs for hypertension treatment in children.

Asthma

Data from the medical literature, clinical trials, and experience were presented and discussed by experts in the field of Pediatric Asthma. Gaps in knowledge in this field include gaps in measuring efficacy and safety of treatments and drug delivery systems, especially in young children. There is also a need for the development of new tools to identify symptom measures, pulmonary function tests, biomarkers, and genetics.

Neonatal Research

There are many areas in the field of neonatal medicine that can benefit from advances in neonatal research. Such gaps in research include areas such as determining feasibility of studying specific drugs in low-birth-weight infants based on current use; the development of novel study designs that take into account the small number of patients available due to either ethical limitations and/or feasibility issues; and the performance of clinical studies in areas such as the treatment of pain, neonatal seizures, and bronchopulmonary dysplasia, based on templates that are being developed by experts in research such as the working groups of the Newborn Drug Development Initiative.

For the coming year, NICHD is planning a series of discussions with experts in the fields listed above and plans to identify and work with experts in these respective fields along with our continuing discussions with the other NIH Institutes and Centers. The goal of all of these discussions will be to specifically identify current gaps in scientific knowledge regarding research and treatment of these various pediatric conditions with the ultimate goal of determining future approved drugs for which pediatric studies are needed.

Dated: March 15, 2007.

Raynard S. Kington,

Deputy Director, National Institutes of Health.

[FR Doc. E7–5673 Filed 3–27–07; 8:45 am]

BILLING CODE 4140–01–P

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.

Microarray for Detection and Subtyping of Human Influenza Viruses

Description of Technology: Available for licensing and commercial development are a novel influenza virus microarray and methods for using the microarray for the identification of existing and new types and subtypes of human influenza viruses. There are three types of influenza viruses, type A, B and C. Influenza types A or B viruses cause epidemics of disease almost every winter, with type A causes major pandemic periodically. Influenza type A viruses are further divided into subtypes based on two proteins on the surface of the virus. These proteins are called hemagglutinin (H) and neuraminidase (N). There are 16 known HA subtypes and 9 known NA subtypes of influenza A viruses. Each subtype may have different combination of H and N proteins. Although there are only three known A subtypes of influenza viruses (H1N1, H1N2, and H3N2) currently circulating among humans, many other different strains are circulating among birds and other animals and these viruses do spread to humans occasionally. There is a requirement for sensitive and rapid diagnostic techniques in order to improve both the diagnosis of infections and the quality of surveillance systems. This microarray platform tiles the genomes of all types/subtypes of influenza viruses, and is capable of correctly identifying all 3 types/subtypes of influenza viruses from an influenza vaccine sample.

More specifically, the invention consists of: (1) Microarrays comprising a solid support with a plurality of n-mer influenza viral nucleotide segments of influenza Types A, B and C, including each respective subtypes, and (2) methods of detecting and identifying known and unknown influenza viral types and subtypes by: (a) Using hybridization microarrays to known influenza viral nucleotide sequences, (b) sequencing the nucleotides which hybridize to the microarrays and (c) analyzing the hybridized sequences using existing databases, thus identifying existing or new subtypes of influenza viruses.

Applications: Detection and identification of human influenza viruses; Efficient discovery of new subtypes of influenza viruses; Diagnosis of influenza outbreaks.

Development Status: This microarray platform was capable of correctly identifying all 3 types/subtypes of influenza viruses from an influenza vaccine sample.

Inventors: Xiaolin Wu, Cassio S. Baptista, Elizabeth Shannon, and David J. Munroe (NCI).

Patent Status: U.S. Provisional Application No. 60/857,695 filed 07 Nov 2006 (HHS Reference No. E–208–2006/0–US–01).

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

Licensing Contact: Cristina Thalhammer-Reyero, PhD, MBA; 301/435–4507; *thalhamc@mail.nih.gov.*

Improved Interleukin Expression for Immunogenic Compositions and Vaccine Adjuvant

Description of Technology: The NIH is pleased to announce as available for licensing a technology that provides for optimized nucleic acids for improved expression of interleukin-15 (IL-15) and IL-15 receptor alpha (IL-15Ralpha) in mammalian cells. IL-15 is a cytokine important for both the innate and adaptive immune systems. Based on its many functions and relative safety in animal models, IL-15 finds use in vaccines, cancer immunotherapeutics, and autoimmune disease and as a vaccine adjuvant.

The present technology enhances the production and bioavailability of IL-15 through use of optimized nucleic acid sequences. Native IL-15 coding sequences do not express IL-15 optimally for several reasons, and the optimized sequences of the subject technology overcome these deficiencies. The nucleic acids can be part of expression vectors, which could be utilized either in vitro or in vivo. The expression vectors express IL-15 alone, IL-15Ralpha alone, or both molecules together from a single vector. Further enhanced expression of IL-15 and/or IL-15Ralpha can be achieved through the use of signal peptides or propeptides from heterologous proteins. These nucleic acids can be administered to enhance the immune response of an individual against one or more antigens. Primate studies have shown that co-administration of IL-15 and IL-15Ralpha increased antigen specific cells, cells expressing IL-2, and/or cells expressing IL-2 and IFN-gamma (i.e. multifunctional cells). The present compositions are useful for the increased bioavailability and therefore biological effects of IL-15 after its administration to humans or other mammals.

Applications: Vaccines; Improved protein expression; Cancer immunotherapeutics; Autoimmune disease; Vaccine adjuvant.

Inventors: Barbara K. Felber and George N. Pavlakis (NCI).

Related Publication: MA Kutzler *et al.* Coimmunization with an optimized IL-15 plasmid results in enhanced function and longevity of CD8 T cells that are partially independent of CD4 T cell help. J Immunol. 2005 Jul 1;175(1):112–123.

Patent Status: U.S. Provisional Application No. 60/758,819 filed 13 Jan 2006 (HHS Reference No. E–254–2005/0–US–01); U.S. Provisional Application No. 60/812,566 filed 09 Jun 2006 (HHS Reference No. E–254–2005/1–US–01); PCT Application filed 13 Jan 2007 (HHS Reference No. E–254–2005/2–PCT–01).

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

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

Potent Activation of Antigen Presenting Cells by the Hepatitis A Virus Cellular Receptor 1 and Its Role in the Regulation of Immune Responses

Description of Technology: Available for licensing and commercial development are compositions and methods to regulate various immune responses through the hepatitis A virus cellular receptor 1 (HAVCR1). HAVCR1 (also known as TIM-1) is a member of the TIM family of receptors that is usurped by the hepatitis A virus (HAV) to infect cells. The gene encoding HAVCR1 has been shown to be an important asthma and allergy susceptibility gene. HAVCR1 plays a critical role in regulating T cell differentiation and the development of atopy. HAVCR1 is over-expressed in kidney ischemic cells and malignant renal tumors. The invention describes a ligand of HAVCR1 in antigen presenting cells (APCs) that is unrelated to murine Tim-4, a TIM family member reported as the ligand of murine Tim-1. The ligand was identified using an expression cloning strategy. The specific binding of HAVCR1 to this ligand on APCs causes activation and induces the expression of co-stimulatory receptors at the cell surface of the APCs and the secretion of cytokines such as IL-6, IL-10, and TNF-a. Furthermore, treatment of APCs with soluble forms of HAVCR1 induced T cell proliferation. The invention describes a novel mechanism by which HAVCR1 regulates immune responses, in which the activation of APCs is mediated by HAVCR1 binding to ligands on APCs. The association of HAVCR1 with the ligand identified in

APCs also enhances the interaction of HAVCR1 with HAV.

Aspects of the technology are further described in Tami *et al.*, 2007. J. Virol., in press.

Applications: Therapies that target the interaction of HAVCR1 with the ligand on APCs, such as small molecules or monoclonal antibodies, can control immune responses, the development of asthma, allergies and other atopic diseases, hepatitis A, kidney regeneration, and cancer.

Development Status: The technology is in early stages of development.

Inventors: Gerardo Kaplan (CBER/FDA), *et al.*

Patent Status: U.S. Provisional Application No. 60/865,631 filed 13 Nov 2006 (HHS Reference No. E–035–2005/0–US–01).

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

Licensing Contact: Cristina Thalhammer-Reyero, PhD, M.B.A.; 301/435–4507; *thalhamc@mail.nih.gov.*

Collaborative Research Opportunity: The Food and Drug Administration, Center of Biologics Research and Evaluation, Laboratory of Hepatitis and Related Emerging Agents, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the hepatitis A virus cellular receptor as a potent activator of antigen presenting cells. Please contact Beatrice Droke, 301/872–7008 or *beatrice.droke@fda.hhs.gov,* for more information.

Cyanovirins and Related Conjugates, Compositions, Nucleic Acids, Vectors, Host Cells, Methods of Production and Methods of Use for Microbicide Development

Description of Technology: The development of an effective anti-HIV topical microbicide, especially a female-controlled, vaginal microbicide, has been deemed an urgent global priority by numerous international agencies, including the World Health Organization, the U.S. Department of Health and Human Services, the National Institute of Allergy and Infectious Diseases, and others. The present invention provides antiviral proteins (collectively referred to as cyanovirins), conjugates thereof, DNA sequences encoding such agents, host cells containing such DNA sequences, antibodies directed to such agents, compositions comprising such agents, and methods of obtaining and using such agents for the production of microbicides.

Cyanovirin-N (CV-N) potently and irreversibly inactivates diverse primary strains of HIV-1, including M-tropic forms involved in sexual transmission of HIV, as well as T-tropic and dual-tropic forms; CV-N also blocks cell-to-cell transmission of HIV infection. CV-N is directly virucidal, interacting in an unusual manner with the viral envelope, apparently binding with extremely high affinity to poorly immunogenic epitopes on gp120. Further, cyanovirin-N (CV-N) and homologous proteins and peptides potently inhibit diverse isolates of influenza viruses A and B, the two major types of influenza virus that infect humans.

The described technology includes glycosylation-resistant mutants of CV-N, which code sequences to enable ultra large-scale recombinant production of functional cyanovirins in non-bacterial (yeast or insect) host cells or in transgenic animals or plants. Therefore, these glycosylation-resistant mutants may allow industry to produce CV-Ns on a large scale and make CV-Ns cheap enough for developing countries to benefit from this invention.

CV-N was benign in vivo when tested in the rabbit vaginal toxicity/irritancy model, and was not cytotoxic in vitro against human immune cells and lactobacilli (unpublished). CV-N is readily soluble in aqueous media, is remarkably resistant to physicochemical degradation and is amenable to very large-scale production by a variety of genetic engineering approaches.

Applications: Development of microbicides against HIV and influenza.

Development Status: Preclinical data is available at this time.

Inventors: Michael Boyd (NCI), Robert Shoemaker (NCI), Barry O'Keefe (NCI), Toshiyuki Mori (NCI), Angela Gronenborn (NIDDK).

Related Publications:

1. B Giomarelli, R Provvedi, F Meacci, T Maggi, D Medaglini, G Pozzi, T Mori, JB McMahon, R Gardella, MR Boyd. The microbicide cyanovirin-N expressed on the surface of commensal bacterium Streptococcus gordonii captures HIV-1. AIDS. 2002 Jul 5;16(10):1351–1356.

2. CC Tsai, P Emau, Y Jiang, MB Agy, RJ Shattock, A Schmidt, WR Morton, KR Gustafson, MR Boyd. Cyanovirin-N inhibits AIDS virus infections in vaginal transmission models. AIDS Res Hum Retroviruses. 2004 Jan;20(1):11–18.

Patent Status:

1. Patent Cooperation Treaty Serial No. PCT/US00/06247 filed 10 Mar 2000; National Stage Filing in United States, Japan, Australia, Europe, Germany, France, China, United Kingdom, and Belgium (HHS Reference No. E–074–1999/2).

2. Patent Cooperation Treaty Serial No. PCT/US99/18975 filed 19 Aug 1999; National Stage Filing in United States, Japan, Australia, Europe, Germany, France, China, United Kingdom, and Belgium (HHS Reference No. E–117–1995/3).

Licensing Status: Available for licensing and commercial development.

Licensing Contact: Sally Hu, PhD; 301/435–5606; *HuS@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute's Molecular Targets Development Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize microbicides for HIV and influenza. Please contact John D. Hewes at (301) 435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: March 16, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–5670 Filed 3–27–07; 8:45 am]

BILLING CODE 4140–01–P

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.

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