


Licensing Contact: Whitney Hastings, M.S.; 301–451–7337; hastingw@mail.nih.gov.

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Cellular and Molecular Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John Hewes, Ph.D. at 301–435–3131 or hewesj@mail.nih.gov for more information.

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.

New Mouse Strain With Conditional Deletion of SMAD7: Analysis of Disease Processes Involving Immunological, Fibrotic or Cardiovascular Indications

Description of Invention: SMAD7 conditional knockout mice are available for licensing. SMAD7 can be knocked out by breeding with CRE-recombinase transgenic mice with a variety of promoters to yield tissue or cell type-specific deletions of SMAD7. SMAD7 has been shown to play a role in bone morphogenesis, cardiovascular tissue generation, immune regulation and fibrosis. Therefore, these mice provide a unique model to examine the role of the SMAD7 gene in disease processes that involve immunological, fibrotic, or cardiovascular components.

Specifically, these mice may represent a novel model of Scleroderma, a disease with both an immunological and fibrotic component.

Applications:

• Mouse model of Scleroderma.
• Means of studying bone morphogenesis and cardiovascular tissue generation.
• Means of studying the role of SMAD7 in immune regulation.

Inventors: Marilyn Diaz (NIEHS).


Patent Status: This technology is available as a research tool under a Biological Materials License.

Collaborative Research Opportunity: The NIEHS is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Dr. Elizabeth M. Denholm, denholme@niehs.nih.gov, for more information.

A Method of Reducing Cholesterol Biosynthesis With Specific MicroRNAs

Description of Invention: This technology is directed to the discovery of specific microRNAs that target and downregulate enzymes within the cholesterol biosynthetic pathway and is currently being tested in vivo.

Briefly, microRNAs regulate the translation of messenger RNAs (mRNAs)
into protein. The inventors have discovered a set of specific microRNAs that downregulate the expression of multiple enzymes in the cholesterol biosynthetic pathway. Importantly, this technology may provide the benefits of lowering cholesterol therapies to patients that are not suited for statin-based treatments. Statins block the cholesterol biosynthetic pathway at a single enzymatic step and may result in the deleterious build-up of a metabolic intermediate. In contrast, this technology simultaneously targets the expression of multiple enzymes required for cholesterol biosynthesis and thus may avoid the build-up of metabolic intermediates. The reduction of cholesterol biosynthesis has been indicated for improved cardiovascular health and lowers the risk for heart disease, heart attack, and stroke.

Potential Applications and Advantages:
- A method of reducing cellular cholesterol biosynthesis.
- A method of reducing systemic cholesterol in a subject.
- May be effective for patients not suited for statin-based treatment.
- Targets multiple enzymes in the cholesterol biosynthetic pathway simultaneously.

Development Status: Early stage.
Market: According to the Centers for Disease Control (CDC), approximately one in every six adults has high cholesterol and individuals with high total cholesterol have approximately twice the risk of heart disease in comparison to individuals with optimal levels.

Inventors: Kasey Vickers and Alan Remaley (NHLBI).


Licensing Status: Available for licensing.

Contact: Fatima Sayyid, MHPM; 301–435–4521; Fatima.Sayyid@nih.hhs.gov.

Collaborative Research Opportunity: The National Heart, Lung and Blood Institute, Pulmonary Vascular Medicine Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize microRNA regulation of the cholesterol biosynthetic pathway.
Please contact Dr. Denise M. Crooks at 301–435–0103, crooksd@nhlbi.nih.gov for more information.

Moraxella Catarrhalis Lipopoligosaccharide Based Conjugate Vaccines for the Prevention of Otitis Media and Respiratory Infections

Description of Invention: Moraxella catarrhalis is one of the three leading causative agents of otitis media in children. This is due in part to the current immunizations of children with Streptococcus pneumoniae polysaccharide and conjugate vaccines to prevent otitis media. The proportion of otitis media caused by pneumococcal strains covered by the vaccines have decreased while those caused by Moraxella catarrhalis and nontypeable Haemophilus influenzae have significantly increased. At some point during early childhood, otitis media affects more than 80% of children under 6 years of age. Otitis media can lead to deafness and language or learning deficits. In adults, Moraxella catarrhalis is a major cause of bronchopneumonia and exacerbation of existing chronic obstructive pulmonary disease for chronic heavy smokers or elderly patients with chronic pulmonary disease. Moraxella catarrhalis infections can be treated with antimicrobial agents; however, the emergence of antibiotic resistance makes vaccines against Moraxella catarrhalis an attractive alternative to antimicrobial drugs. There are currently no Moraxella catarrhalis vaccines on the market.

The subject technologies are conjugate vaccines against Moraxella catarrhalis. The vaccines are comprised of isolated lipopoligosaccharides (LOS) from which esterified fatty acids have been removed to produce detoxified LOS or from which lipid A has been removed to produce a detoxified oligosaccharide (OS) covalently linked to an immunogenic carrier such as tetanus toxoid, and adjuvants such as alum. The vaccines can potentially be used as a vaccine component in a combination vaccine containing other pediatric vaccine components.

Applications: Vaccines for the prevention of respiratory infections and otitis media caused by Moraxella catarrhalis.

Advantages:
- Novel vaccine candidates.
- LOS is a conserved antigen.

Development Status: In vitro and in vivo (mouse animal model) data is available and can be provided upon request.
Market:
- Pediatric vaccines.
- Preventative vaccines.

Inventors: Xin-Xing Gu (NIDCD) and John Robbins (NICHD).

Related Publications: Manuscripts in preparation, available upon request under a confidential disclosure agreement.

Patent Status:

Licensing Status: Available for licensing.

Contact: Kevin W. Chang, Ph.D.; 301–435–5018; changke@mail.nih.gov.

Collaborative Research Opportunity: The National Institute on Deafness and Other Communication Disorders, Vaccine Research Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the subject technology.

Please contact Brian W. Bailey, Ph.D. at 301–594–4094 or bbailey@mail.nih.gov for more information.

Nontypeable Haemophilus Influenzae Lipopoligosaccharide Based Conjugate Vaccines for the Prevention of Otitis Media and Respiratory Infections

Description of Invention: Nontypeable Haemophilus influenzae is one of the leading causative agents of otitis media in children and accounts for 11% of pneumonia cases in children. This is due in part to the current immunizations of children with Streptococcus pneumoniae polysaccharide and conjugate vaccines to prevent otitis media. The proportion of otitis media caused by pneumococcal strains covered by the vaccines have decreased while those caused by nontypeable Haemophilus influenzae have significantly increased. At some point during early childhood, otitis media affects more than 80% of children under 6 years of age. Otitis media can lead to deafness and language or learning deficits. In adults, nontypeable Haemophilus influenzae causes respiratory tract infections primarily in persons with chronic obstructive pulmonary disease, one of the most common lung diseases.

Exacerbation of chronic obstructive pulmonary disease in the elderly is the fourth leading cause of death in the United States. Otitis media can be treated with antibiotics; however, the emergence of antibiotic resistance makes vaccines against nontypeable Haemophilus influenzae an attractive alternative to those classes of drugs.
current \textit{Haemophilus influenzae} type b conjugate vaccines have no protective effect against nontypeable strains.

The technologies described herein are conjugate vaccines against nontypeable \textit{Haemophilus influenzae}. The vaccines are comprised of lipooligosaccharides (LOS) from which esterified fatty acids have been removed from lipid A to form detoxified LOS conjugated to an immunogenic carrier such as tetanus toxoid, and an adjuvant such as alum. \textit{In vivo} data in the Chinchilla animal model are available. The vaccines can be potentially used as a component in a combination vaccine with other pediatric vaccine components.

Applications: Vaccines for the prevention of respiratory infections and otitis media caused by nontypeable \textit{Haemophilus influenzae}.

Advantages:
\begin{itemize}
\item Novel vaccine candidates.
\item Conserved antigen.
\end{itemize}

Development Status: \textit{In vitro} and \textit{in vivo} data can be provided upon request. Data is also available from a phase I clinical trial with a representative vaccine showing safety and immunogenicity in adults.

Market:
\begin{itemize}
\item Pediatric vaccines.
\item Preventative vaccines.
\end{itemize}

Inventors: Xin-xing Gu (NIDCD), John Robbins (NICHD), et al.

Related Publication: W Hong et al. Protection against nontypeable Haemophilus influenzae challenges by mucosal vaccination with a detoxified lipooligosaccharide conjugate in two chinchilla models. 


Patent Status:
\begin{itemize}
\end{itemize}

Licensing Status: Available for licensing.

Licensing Contact: Kevin W. Chang, Ph.D.; 301–435–5018; changke@mail.nih.gov.

Collaborative Research Opportunity:
The National Institute on Deafness and Other Communication Disorders, Vaccine Research Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the subject technology. Please contact Brian W. Bailey, Ph.D. at 301–594–4094 or bbailey@mail.nih.gov for more information.


Richard U. Rodriguez, 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

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Cellular & Tissue Biology P01.

Date: May 26–28, 2010.

Time: 7 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Shakeel Ahmad, PhD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8139, Bethesda, MD 20892–8328, (301) 594–0114, ahmads@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Community Tobacco Control Policy and Media Research.

Date: May 26–27, 2010.

Time: 7 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Legacy Hotel and Conference Center, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Gerald G. Lovinger, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8101, Bethesda, MD 20892–8329, 301/496–7987, lovingeg@mail.nih.gov.


Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Closed Meeting

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The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.