ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual hour burden
FY 2014				
Clinical Center Patients	5000	1	30/60	2500
Family Members of Patients	2000	1	30/60	1000
Visitors to the Clinical Center	500	1	10/60	84
NIH Intramural Collaborators	2000	1	10/60	334
Vendors and Collaborating Commercial Enterprises	500	1	20/60	167
Professionals and Organizations Referring Patients	2000	1	20/60	667
Regulators	30	1	20/60	10
Volunteers	275	1	30/60	138
FY 2015				
Clinical Center Patients	5000	1	30/60	2500
Family Members of Patients	2000	1	30/60	1000
Visitors to the Clinical Center	500	1	10/60	84
NIH Intramural Collaborators	2000	1	10/60	334
Vendors and Collaborating Commercial Enterprises	500	1	20/60	167
Professionals and Organizations Referring Patients	2000	1	20/60	667
Regulators	30	1	20/60	10
Volunteers	275	1	30/60	138
FY 2016				
Clinical Center Patients	5000	1	30/60	2500
Family Members of Patients	2000	1	30/60	1000
Visitors to the Clinical Center	500	1	10/60	84
NIH Intramural Collaborators	2000	1	10/60	334
Vendors and Collaborating Commercial Enterprises	500	1	20/60	167
Professionals and Organizations Referring Patients	2000	1	20/60	667
Regulators	30	1	20/60	10
Volunteers	275	1	30/60	138

Dated: January 14, 2014.

David K. Henderson,

Deputy Director for Clinical Care, CC, National Institutes of Health.

[FR Doc. 2014–01343 Filed 1–22–14; 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, 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. 209 and 37 CFR part 404 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.

FOR FURTHER INFORMATION CONTACT: 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.

Improved Therapeutic Immunotoxins

Description of Technology: Immunotoxins kill cancer cells while allowing healthy, essential cells to survive. As a result, patients receiving immunotoxins are less likely to experience the deleterious side-effects associated with non-discriminate therapies, such as chemotherapy or radiation therapy. Unfortunately, the continued administration of immunotoxins often leads to a reduced patient response due to the formation of neutralizing antibodies against immunogenic epitopes contained within the toxin. One such toxin is Pseudomonas exotoxin A (PE). To improve the therapeutic effectiveness of PE-based immunotoxins through multiple rounds of drug administration, NIH inventors previously reduced the immunogenicity of PE through the removal of B-cell and T-cell epitopes by mutation or deletion. Although this resulted in immunotoxins with improved therapeutic activity, the modifications to reduce immunogenicity decreased the activity of PE. Through further specific modification, the inventors have now created a PE that has reduced immunogenicity with limited loss of activity. The resulting PE-based immunotoxins have increased resistance to the formation of neutralizing antibodies, while retaining greater activity, and are expected to have improved therapeutic efficacy.

Potential Commercial Applications:

- Essential payload component of immunotoxins
- Treatment of any disease associated with increased or preferential expression of a specific cell surface receptor
- Specific diseases include hematological cancers, lung cancer, ovarian cancer, breast cancer, and head and neck cancers

Competitive Advantages:

• New modifications allow for the reduction of immunogenicity with less loss of activity
• Less immunogenic immunotoxins with greater activity results in improved therapeutic efficacy by permitting multiple rounds of administration in humans
• Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer non-specific side-effects and healthier patients

Development Stage:
• Early-stage
• In vitro data available
• In vivo data available (animal)

Inventors: Ira H. Pastan et al. (NCI)

Intellectual Property:
• HHS Reference No. E–771–2013/0—U.S. Provisional Patent Application No. 61/887,418 filed 06 October 2013
• HHS Reference No. E–771–2013/1—U.S. Provisional Patent Application No. 61/908,464 filed 25 November 2013

Related Technologies:
• HHS Reference No. E–117–2011/0—PCT Patent Publication WO 2012/154530
• HHS Reference No. E–174–2011/0—PCT Patent Publication WO 2012/170617
• HHS Reference No. E–263–2011/0—PCT Patent Publication WO 2012/032022
• HHS Reference No. E–269–2009/0—US Patent Publication 20120263674 A1
• HHS Reference No. E–292–2007/0—US Patent Publication US 20100215656 A1
• HHS Reference No. E–262–2005/0—US Patent Publication US 20090142341 A1
• Multiple additional patent families

Licensing Contact: David A. Lambertson, Ph.D.; 301–435–4632; *lambertsond@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research, Laboratory of Molecular Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize a new immunotoxin target. For collaboration opportunities, please contact John D. Hewes, Ph.D., at *hewesj@mail.nih.gov*.

Respiratory Syncytial Virus Vaccines Based on G Protein Subunit

Description of Technology: The invention pertains to cross-neutralizing vaccines against human respiratory syncytial virus subtypes A and B employing immunogenic G protein subunit and fragments thereof that are preferably derived from the ectodomain. Various candidate G protein subunits are provided spanning amino acid sequence 67–298 of RSV G protein and combinations thereof. Also envisioned within the scope of this invention are tandem repeated recombinant G protein subunit vaccines that provide higher immunogenicity. Recombinant G protein can be codon optimized for expression in various hosts (e.g., mammalian cells or *E. coli*).

Potential Commercial Applications:
• Vaccine
• Childhood vaccines

Competitive Advantages: Cross neutralizing

Development Stage:
• Early-stage
• In vitro data available

Inventors: Surender Khurana and Hana Golding (FDA)

Intellectual Property: HHS Reference No. E–735–2013/0—U.S. Provisional Patent Application No. 61/863,100 filed 02 December 2013

Licensing Contact: Michael Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov*

Collaborative Research Opportunity: The Food and Drug Administration, Center for Biologics Evaluation and Research, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize RSV G protein subunit vaccine. For collaboration opportunities, please contact Surender Khurana, Ph.D., at 301–827–0739.

Pyrrole Derivative Inhibitors of Wip1 for the Treatment of Cancer

Description of Technology: Wild-type p53-induced phosphatase 1 (Wip1) is an enzyme that is overexpressed in a number of human cancers, including breast cancer, neuroblastoma and ovarian cancer. Wip1 has a suppressive effect on the tumor suppressor p53, allowing the unregulated growth that is associated with tumors. Inhibiting Wip1 could restore the tumor suppressor activity of p53, leading to the arrest of unregulated tumor growth and induction of apoptosis. This suggests that inhibitors of Wip1 could be of therapeutic value for the treatment of cancer.

This invention concerns novel small molecules that can inhibit Wip1 activity. The particular structure of the small molecules allows for specific targeting to Wip1. Specifically, the structure is a derivative of a pyrrole ring having five (5) points of substitution. These small molecules have the ability to significantly inhibit Wip1 phosphatase activity at the micromolar level, with substitutions of biphenyl groups having the highest level of inhibition. Based on their potential ability to restore the activity of a tumor suppressor protein and activate apoptosis, these small molecules may be useful in the treatment of cancers that overexpress Wip1.

Potential Commercial Applications:
• Treatment of cancer, including but not limited to breast cancer, ovarian cancer and neuroblastoma
• Can be used either alone or in combination with other known anti-cancer therapeutics

Competitive Advantages:
• Structure of the inhibitor allows specific targeting of Wip1, possibly leading to fewer undesired effects during treatment
• The molecules are designed to be more stable and effectively penetrate mammalian cells
• The current lack of Wip1 inhibitors can lead the occupation of a significant position in the cancer therapeutic market with a first-in-class drug

Development Stage: Early-stage

Inventors: Daniel H. Appella et al. (NIDDK)

Publication: Hayashi R, et al. Optimization of a cyclic peptide inhibitor of Ser/Thr phosphatase PPM1D (Wip1). Biochemistry. 2011 May 31;50(21):4537–49. [PMID 21528848]

Intellectual Property: HHS Reference No. E–537–2013/0—U.S. Provisional Patent Application No. 61/865,845 filed 14 August 2013

Related Technology: HHS Reference No. E–302–2007/0—US Patent Application No. 12/675,167 filed 25 February 2010

Licensing Contact: David A. Lambertson, Ph.D.; 301–435–4632; *lambertsond@mail.nih.gov*

Methods of Treating or Preventing Pruritis (Itch)

Description of Technology: This technology provides a novel method of treating or preventing pruritis (itch) using natriuretic polypeptide b (Nppb) blocking agents. Itch (also known as pruritis) is a sensation that may be perceived as an unpleasant skin irritation and may drive an urge to scratch. Conditions such as, for example, psoriasis, atopic dermatitis, renal failure, liver cirrhosis and some cancers may cause persistent itch. Itch is triggered by somatosensory neurons expressing the ion channel TRPV1 (transient receptor potential cation channel subfamily V member 1). The inventors of this technology show that the Nppb is expressed in a subset of TRPV1 neurons and found that Nppb–/– mice selectively lose all behavioral responses to itch-inducing agents. Nppb triggered potent scratching when

injected intrathecally in wild-type and Nppb–/– mice. Itch responses were blocked by toxin-mediated ablation of Nppb-receptor-expressing cells, but a second neuropeptide, gastrin-releasing peptide, still induced strong responses in the toxin-treated animals.

Potential Commercial Applications:

• Therapeutics for preventing or treating pruritis/itching.

• Screening of novel Nppb blocking agents.

Competitive Advantages: A new mode of treating itch and itch induced conditions using selective Nppb antagonists.

Development Stage:

• Early-stage

• In vitro data available

Inventors: Mark A. Hoon and Santosh K. Mishra (NIDCR)

Publication: Mishra SK, Hoon MA. The cells and circuitry for itch responses in mice. Science. 2013 May 24;340(6135):968–71. [PMID 23704570]

Intellectual Property: HHS Reference No. E–485–2013/0—U.S. Provisional Patent Application No. 61/912,334 filed 05 December 2013

Licensing Contact: Suryanarayana (Sury) Vepa, Ph.D., J.D.; 301–435–5020; *vepas@mail.nih.gov*

Recombinant Stabilized Prefusion Protein of Respiratory Syncytial Virus for Use as a Subunit Vaccine

Description of Technology: The invention, a stabilized recombinant prefusion F protein (pre F), is a candidate subunit vaccine for Respiratory Syncytial Virus (RSV). Pre-F is stabilized in the prefusion conformation and displays epitopes not present in postfusion F protein. Several potent RSV neutralizing antibodies bind pre F, but not postfusion F. Therefore, immunization with pre F may elicit an immune response superior to the response generated by postfusion F.

NIH researchers have engineered pre F to expose an antigenic site 0, which is targeted by extremely potent RSV neutralizing antibodies. Structure-based design yielded several stabilized variants of pre F that maintained exposure of antigenic site 0 when subjected to extremes of pH, osmolality and temperature.

Preclinical in vivo data on stabilized pre F is available. Immunization of mice and macaques with antigenic site 0 stabilized pre F variants elicited high levels of RSV specific neutralizing activity.

Potential Commercial Applications: Vaccine for Respiratory Syncytial Virus

Competitive Advantages:

• Vaccine stably exposes antigenic site in RSV F that permits generation of potent RSV neutralizing antibodies.

• There is currently no RSV vaccine on the market.

Development Stage:

• Pre-clinical

• In vivo data available (animal)

Inventors: Jason S. McLellan, Barney S. Graham, Peter D. Kwong (all of VRC/NIAID)

Publications:

1. McLellan JS, et al. Structure of RSV fusion glycoprotein trimer bound to a prefusion-specific neutralizing antibody. Science 2013 May 31;340(6136):1113–7. [PMID 23618766]

2. McLellan JS, et al. Structure-based design of a fusion glycoprotein vaccine for respiratory syncytial virus. Science 2013 Nov 1:342 (6158)592–8. [PMID 24179220]

Intellectual Property:

• HHS Reference No. E–081–2013/0—U.S. Application No. 61/780,910 filed 13 March 2013

• HHS Reference No. E–081–2013/1—U.S. Application No. 61/798,389 filed 15 March 2013

• HHS Reference No. E–081–2013/2—U.S. Application No. 61/857,613 filed 23 July 2013

• HHS Reference No. E–081–2013/3—U.S. Application No. 61/863,909 filed 09 August 2013

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301–435–4507; *ThalhamC@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Vaccine Research Center, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize an RSV vaccine based on pre F, a stabilized recombinant RSV F protein. For collaboration opportunities, please contact Rosemary C. Walsh, Ph.D. at 301–541–3528 or *rcwalsh@niaid.nih.gov*.

Dated: January 16, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014–01186 Filed 1–22–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Hypersensitivity, Autoimmune, and Immune-mediated Disease Overflow.

Date: February 7, 2014.

Time: 8:00 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Jin Huang, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095G, MSC 7812, Bethesda, MD 20892, 301–435–1187, *jh377p@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Liver and Gastrointestinal Physiology & Pathophysiology.

Date: February 11, 2014.

Time: 1:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Martha Garcia, PhD., Scientific Reviewer Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, Bethesda, MD 20892, 301–435–1243, *garciamc@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular Neuroscience.

Date: February 13, 2014.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Laurent Taupenot, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4811, MSC 7850, Bethesda, MD 20892, 301–435–1203, *taupenol@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Developmental Brain Disorders Study Section.

Date: February 20–21, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Hilton Woodland Hills/Los Angeles, 6360 Canoga Avenue, Woodlands Hills, CA 91367.