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 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 20852–3904; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Use of Antihistamine Compounds for the Treatment of Hepatitis C Virus

Description of Technology: The vast majority of people infected with Hepatitis C Virus (HCV) will have chronic infection. Over decades, this can lead to liver disease and liver cancer. In fact, HCV infection is the leading cause of liver transplants in the U.S. Several new drugs have recently come into the market that will likely change the HCV treatment paradigm. However, the effectiveness of these new drugs can vary depending on the HCV genotype. Thus, there is still the need for additional new therapeutics against HCV.

The subject technology are small molecule compounds identified using a novel cell-based high throughput assay of HCV infection. The compounds are antihistamines that show potent antiviral properties against HCV. One advantage of these compounds is that they are already on the market for the treatment of allergic reactions and, thus, have been used extensively in humans and have excellent safety profiles with known pharmaceutical properties. The subject technology can also potentially be used in combination with other HCV therapeutics.

Potential Commercial Applications: Prevention or treatment of HCV infection.

Competitive Advantages: These compounds are already on the market and, thus, have known safety profiles and pharmaceutical properties.

Development Stage

• Early-stage
• In vitro data available

Inventors: Jake Tsanyang Liang (NIDDK), Juan Jose Marugan (NCATS), Noel Terrance Southall (NCATS), Xin Hu (NCATS), Jingbo Xiao (NCATS), Shanshan He (NIDDK), Marc Ferrer (NCATS), Zongyi Hu (NIDDK), Wei Zhang (NCATS)


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

Intranasal Nebulizer With Disposable Drug Cartridge for Improved Delivery of Vaccines and Therapeutics

Description of Technology: Intranasal delivery is a simple, inexpensive and needle-free route for administration of vaccines and therapeutics. This intranasal delivery technology, developed with Creare LLC, includes low-cost, disposable drug cartridges (DDCs) that mate with a durable handheld device. The rechargeable-battery-powered device transmits ultrasonic energy to the DDC to aerosolize the drug and is capable of performing for eight hours at 120 vaccinations per hour. Potential applications for this platform technology include intranasal vaccination (e.g. seasonal or pandemic influenza vaccines) and intranasal delivery of locally active (e.g. antihistamines, steroids) or systemically active (e.g. pain medications, sedatives) pharmaceuticals.

The DDCs themselves offer two unique benefits. First, all components that contact the active agent or the patient may be easily disposed of, which reduces the risk of patient cross-contamination and minimizes cleaning and maintenance requirements of the hand-held device. Second, DDCs provide a low-cost and simple method to package and distribute individual doses.

This technology also allows for significant dose-sparing. Preliminary studies have shown robust immune responses when this technology is used to delivery significantly reduced doses of Live Attenuated Influenza Vaccine in animal models. The intranasal nebulizer produces droplets sized for optimum deposition in the nasal airway. The small nebulizer droplets essentially “spray paint” the internal nasal airway, resulting in an increased tissue surface coverage that may enable a significant dose reduction. In contrast, currently available nasal delivery devices, such as nasal sprays and droppers, do not provide efficient intranasal delivery in humans because the large droplets they generate fail to coat a significant portion of the nasal airway. Large droplets also tend to drip out of the nose or down the throat, which can be unpleasant for the patient in addition to wasting a sizable portion of the active agent.

Potential Commercial Applications

• Intranasal delivery of vaccines and therapeutics
• Childhood vaccination programs, mass immunization campaigns, or response to epidemics

Competitive Advantages

• Safe, needle-less delivery
• No patient-to-patient contamination
• Long-life, rechargeable battery
• Consistent delivery and dose-sparing
• Nasal delivery of live-attenuated vaccines may be more effective than traditional injected vaccines
• Cost-effective
• Reduces biohazard waste
• May be administered by personnel with minimal medical training
• Easy means of delivery to children with fear of needles

Development Stage

• Prototype
• In vitro data available
• In vivo data available (animal)

Inventors: Mark J. Papania (CDC), et al.

vaccine provides protection in ferrets at a reduced dose. Vaccine. 2012 Apr 19;30(19):3026–33. [PMID 22075083]

**Intellectual Property**

- Various international pending patents
- Various international issued patents
- US Patent No. 8,544,462 issued 01 Oct 2013
- Various international issued patents
- Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**Silica Exposure Safety: Mini-Baghouse Systems and Methods for Controlling Particulate Release From Large Sand Transfer Equipment**

**Description of Technology:** CDC/NIOSH scientists have developed an effective point-source control for silica-containing dusts that can be generated from machinery on sites where hydraulic fracturing is occurring. The CDC/NIOSH mini-baghouse retrofit assembly is a bolt-on control designed to contain silica-containing respirable dusts generated during refill operations of sand movers during hydraulic fracturing.

In the U.S., most new oil and gas wells are hydraulically fractured to enhance well production. Most hydraulic fracturing operations have 2–5 sand movers on-site which transfer thousands to millions of pounds of silica sand during each stage of fracturing. While a variety of passive and active controls are currently available (or have been proposed) to limit release of silica-containing dusts, the CDC/NIOSH mini-baghouse retrofit assembly was designed to fill a unique need for a control. The retrofit to equipment can be made in the field, uses existing energy inherent in the system and is relatively simple and effective. CDC/NIOSH field research has shown that risks for exposure to respirable silica arise from at least 8 points of dust generation and that a variety of controls (engineering, administrative and personal protective equipment) are needed to control exposures. Use of the mini-baghouse retrofit technology is intended to limit release of respirable silica from thief hatches on top of the sand movers, enhancing workplace health and safety.

**Potential Commercial Applications**

- Controlling occupational exposure to respirable crystalline silica, particularly during work involving transfer of sand into sand movers on hydraulic fracturing sites
- In-field retrofits of currently operating heavy equipment (e.g., sand movers)
- Limiting visible dust emissions from sand moving equipment
- Reducing respirable crystalline silica dust emissions to enhance compliance with OSHA PEL for silica

**Competitive Advantages**

- Designed for in-field retrofitting “thief hatches” of existing machinery
- Uses energy inherent in the pneumatic transfer of sand
- Provides a passive sand-mover-mounted control for silica release at hydraulic fracturing operations

**Development Stage**

- In situ data available (on-site)
- Prototype

**Inventors:** Eric J. Esswein, Michael Breitenstein, John E. Snawder, Michael G. Gressel, Jerry L. Kratzer (all of CDC)

**Publication:** Esswein EJ, et al.


**Licensing Contact:** Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**Viral Like Particles Based Chikungunya Vaccines**

**Description of Technology:** Chikungunya virus (CHIKV) is mosquito-borne alphavirus endemic in Africa, India, and Southeast Asia. In 2013 CHIKV infection has also emerged in the Caribbean and epidemic of CHIKV has re-emerged in the Philippines following Typhoon Haiyan. Currently, there is no vaccine available for the prevention of CHIKV infection and no specific therapy exists to treat the illness. Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) have developed a CHIKV Viral Like Particle (CHIKV VLP) vaccine based on plasmid expression vectors encoding structural proteins of the CHIKV virus, which gave rise to CHIKV VLPs in transfected cells. The CHIKV VLPs consist of the core, E1 and E2 proteins and are similar in buoyant density and morphology to replication-competent CHIKV virus. Immunization with CHIKV VLPs elicited neutralizing antibodies against envelope proteins from different CHIKV strains in mouse and nonhuman primate (NHP) models. Monkeys immunized with CHIKV VLPs produced high titer neutralizing antibodies that protected against viremia after high dose challenge. The selected CHIKV VLP vaccine candidate, VRC–CHKVLP059–00–VP, composed of the E1, E2, and capsid proteins from the CHIKV strain 37997, was recently evaluated by the VRC at the NIH Clinical Center for safety, tolerability and immunogenicity in the clinical protocol VRC 311 (ClinicalTrials.gov # NCT01489358), a Phase I, open-label, dose escalation clinical trial. The VRC–CHKVLP059–00–VP vaccine was highly immunogenic, safe, and well-tolerated. VRC researchers have also developed the transient transfection manufacturing process for CHIKV and other alphaviruses, such as Western, Eastern and Venezuelan Equine Encephalitis (WEEVE) viruses. Pre-clinical in vivo mouse and NHP data, Phase 1 clinical trial data and manufacturing data are available.

**Potential Commercial Applications:** Chikungunya vaccines based on viral like particles.

**Competitive Advantages**

- There is currently no CHIKV vaccine on the market.
- VRC–CHKVLP059–00–VP vaccine candidate is highly immunogenic, safe, and well-tolerated.
- Minimal containment requirements for CHIKV VLP manufacturing because live virus production is not required.

**Development Stage**

- In vitro data available
- In vivo data available (animal)
- In vivo data available (human)

**Inventors:** Gary J. Nabel, Wataru Akahata, Srinivas S. Rao (all of VRC/NIAID)
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; PAR13–137: Light at Night.

Date: May 20, 2014.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, selmanom@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Molecular Genetics B Study Section.

Date: May 28–29, 2014.
Time: 5:00 p.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Richard A. Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, (301) 435–1219, currier@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Genome x Environment.

Date: May 29–30, 2014.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Time: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Melinda Jenkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3156, MSC 7770, Bethesda, MD 20892, 301–437–7872, jenkinsm12@mail.nih.gov.

Name of Committee: Immunology Integrated Review Group; Cellular and Molecular Immunology—B Study Section.

Date: May 29–30, 2014.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Betty Hayden, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4206, MSC 7812, Bethesda, MD 20892, 301–435–1223, haydenb@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Social Sciences and Population Studies A Study Section.

Date: May 29, 2014.
Time: 8:30 a.m. to 6:30 p.m.
Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, ryans@csr.nih.gov.


Dated: April 21, 2014.

Melanie J. Gray, Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

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 meeting.

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.