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 invention listed below is owned by an agency of the U.S. Government and is available for licensing 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: Jenish Patel, Ph.D., 240–669–2894; *jenish.patel@nih.gov.* Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Monoclonal Antibodies Against Bacillus Anthracis Antigens

Description of Technology: Anthrax, whether resulting from natural or bioterrorist-associated exposure, is a constant threat to human health. Bacillus anthracis is the causative agent of anthrax. It is surrounded by a polypeptide capsule of poly-gamma-D-glutamic acid (gamma-D-PGA), which is essential for virulence, is poorly immunogenic and has anti-phagocytic properties. Antibodies to the capsule have been shown to enhance phagocytosis and killing of encapsulated bacilli. The lethality of anthrax is primarily the result of the effects of anthrax toxin, which has 3 components: A receptor-binding protein known as ''protective antigen'' (PA) and 2 catalytic proteins known as ''lethal factor'' (LF) and ''edema factor'' (EF). Although production of an efficient anthrax vaccine is an ultimate goal, the benefits of vaccination can be expected only if a large proportion of the population at risk is immunized. The low incidence of anthrax suggests that large-scale vaccination may not be the most efficient means of controlling this disease. In contrast, passive administration of neutralizing human or chimpanzee monoclonal antibody to a subject at risk for anthrax or exposed to anthrax could provide immediate efficacy for emergency prophylaxis against or treatment of anthrax.

Several monoclonal antibodies (mAbs) against gamma-D-PGA, PA, LF and EF of anthrax were isolated from a phage display library generated from immunized chimpanzees. Two anti-PA, and two anti-LF mAbs efficiently neutralized the cytotoxicity of lethal toxin in a macrophage lysis assay. One anti-EF mAb efficiently neutralized edema toxin in cell culture. All of these five neutralizing mAbs protected animals from anthrax toxin challenge. There are two anti-gamma-D-PGA mAbs that showed strong opsonophagocytic killing of bacilli in vitro assays. These two mAbs were also tested for protection of mice challenged with virulent anthrax spores and results showed that both mAbs provided full or nearly full protection. Since chimpanzee immunoglobulins are virtually identical to human immunoglobulins, these chimeric chimpanzee mAbs may have clinically useful applications.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

- Prophylaxis, therapeutics or diagnostics against B. anthracis antigens

Competitive Advantages:

- Strongly neutralizing antibodies
- Known regulatory pathway
- Potential for use as both a prophylaxis and therapy

Development Stage:

- In vivo (animal)

Inventors:

Anti-PGA mAbs: Zhaochun Chen (NIAID), Robert Purcell (NIAID), Rachel Schneerson (NIACHD), Joanna Kubler-kielb (NICHD), Lily Zhongdong Dai (NICHD).

All other mAbs: Zhaochun Chen (NIAID), Stephen Leppla (NIAID), Suzanne Emerson (NIAID), Robert Purcell (NIAID), and Mahtab Moayeri (NIDCR).

Publications:

• Z Chen et al. Efficient neutralization of anthrax toxin by chimpanzee monoclonal antibodies against protective antigen. J Infect Dis. 2006 Mar 1;193(5): 625–633.

• Z Chen et al. Bacillus anthracis Capsular Conjugates Elicit Chimpanzee Polyclonal Antibodies That Protect Mice from Pulmonary Anthrax. Clin Vaccine Immunol. 2015 Aug; 22(8): 902–908.

Intellectual Property: HHS Reference Nos. E–146–2004, E–123–2007 and E–125–2008.

Licensing Contact: To license this technology, please contact Jenish Patel, Ph.D., 240–669–2894; *jenish.patel@nih.gov.*

Dated: February 7, 2020.

Wade W. Green,

Acting Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2020–03443 Filed 2–20–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; The National Drug Abuse Treatment Clinical Trials Network (UG1 Clinical Trial Required).

Date: March 5, 2020.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building, 6001 Executive Blvd., Rockville, MD 20852.

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, 6001 Executive Blvd., Room 4235, MSC 9550, Bethesda, MD 20892–9550, 301–827–5819, *gm145a@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)