[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 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

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Wade W. Green,

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Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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