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.

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: 301–435–3943; fax: 301–451–3946; Eugene O. Major and Maderia at maderiam@mail.nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Transmission-Blocking Malaria Vaccine

Description of Technology: There is no vaccine for malaria, and there is growing resistance to existing anti-malarial drugs. Sexual stage-specific antigens are of interest as vaccine candidates because disruption of these antigens would reduce the fertility and, thus, the infectivity of the parasite.

This invention claims methods and compositions for delivering a Plasmodium P47 vaccine or antibody to P47 to prevent Plasmodium falciparum or Plasmodium vivax malaria. P47 and other antigens have been mentioned as potential transmission-blocking vaccines due to their surface location on gametes. The gene for P47 antigens is also well characterized. Recent discoveries have noted that P47 allows the parasite to suppress or evade the immune system, thereby ensuring the mosquitoes’ survival. Recent discoveries have also shown the mechanism by which P47 enables survival of the parasite by manipulation of the mosquito immune system. Based on the critical role of P47 antigens in transmission, the disruption of the function of P47 by various means can be an innovative and forceful means to control and/or reduce the prevalence of malaria.

Potential Commercial Applications: Malaria vaccine, diagnostic and therapeutic.

Competitive Advantages: • Single protein malaria transmission-blocking vaccine. • Cost-effective, simple manufacturing process for vaccine. • Potentially lower-cost malarial vaccine for developing/developed countries.

Development Stage: • Pre-clinical.

In vitro data available.

In vivo data available (animal).

In vivo data available (human).

In vivo data available (animal).

In vivo data available (human).

In vivo data available.

Pre-clinical.

• Development Stage:

• Cost-effective, simple manufacturing process for vaccine.

• Potentially lower-cost malarial vaccine for developing/developed countries.

• Competitive Advantages:

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• Development Stage:

• Cost-effective, simple manufacturing process for vaccine.

• Potentially lower-cost malarial vaccine for developing/developed countries.

• Competitive Advantages:
Typhoid-Plague Bivalent Vaccine

Description of Technology: *Yersinia pestis* (Y. pestis) bacteria is the causative agent of plague, typically transmitted from animals to humans by the bite of an infected flea. Y. pestis infection of the lungs leads to pneumonic plague, which is highly contagious and generally fatal. Y. pestis is a potential bioterrorist threat agent for which no vaccine yet exists.

This invention claims the generation and development of a candidate oral vaccine against plague. The vaccine consists of a synthetic gene construct that expresses a *Y. pestis* F1–V fusion antigen linked to a secretion signal, resulting in the production of large amounts of the F1–V antigen. The F1–V synthetic gene fusion is housed within Ty21a, an attenuated typhoid fever strain that is licensed for human use as a live oral bacterial vaccine. Ty21a serves as a carrier to deliver the F1–V fusion antigens of the plague bacteria; the combined F1–V fusion in the Ty21a carrier has been shown to stimulate a robust immune response in mice. The possibility of combining the oral plague vaccine of this invention with FDA’s candidate oral anthrax vaccine exists and would result in an easy-to-administer oral delivery system to streamline administration of the vaccine to large numbers of recipients in emergency situations.

Potential Commercial Applications:
- Plague vaccines, therapeutics and diagnostics.

Competitive Advantages:
- Vector is well-characterized.
- Simple manufacturing process.
- Potential low-cost vaccine.

Development Stage:
- Pre-clinical.
- In vitro data available.
- In vivo data available.

Inventors: Dennis J. Kopecko, Manuel A. Osorio, Monica R. Foote (FDA/CBER).

Intellectual Property:
- Pre-clinical. Competitive Advantages: Antibodies are cross-reactive with all four serotypes of dengue. Antibodies are fully human.

Development Stage:
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Dimiter S. Dimitrov and Zhongyu Zhu (NCI).


Licensing Contact: Peter A. Soukas; 301–435–4646; soukas@mail.nih.gov.

Collaborative Research Opportunity: The NCI/CCR/NP is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Cross-Reactive Dengue Fully Human Monoclonal A. For collaboration opportunities, please contact John Hewes, Ph.D. at hewesj@mail.nih.gov.

Typhoid-Plague Bivalent Vaccine

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