4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0148]

Government-Owned Inventions; Availability for Licensing; Influenza virus neuramindase

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The invention listed in this document is owned by an Agency of the U.S. Government and is available for licensing in accordance with Federal regulations to achieve expeditious commercialization of results of Federally funded research and development.

FOR FURTHER INFORMATION CONTACT:

For licensing information and copies of the patent applications: Alice Welch, Technology Transfer Program Office, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4226, Silver Spring, MD 20993, 240-402-2561, FAX: 301-847-3539. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

For parties interested in licensing or collaborative research activities: William Ronnenberg, Technology Transfer Program Office, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4214, Silver Spring, MD 20993, 240-402-4561, William.ronnenberg@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Technology description.

Title of Abstract: Therapeutic and prophylactic anti-Influenza virus neuraminidase 1 (N1) antibody (CD6) with a novel epitope that spans neuramindase (NA) dimers.

Description of Technology: Influenza virus neuramindase (NA) protein is a surface protein that plays an essential role in virus replication. Drugs and antibodies that block NA function can reduce both the symptoms and the length of illness; however, variants of influenza virus are resistant to NA inhibitors. The neuramindase 1 (N1) subtype of NA is important because it is found in the two pandemic H1N1 influenza virus strains (1918 Spanish flu and 2009 swine flu) and the H5N1 avian influenza virus. Anti-neuramindase antibody CD6 is a novel antibody that spans a conserved 30 amino acid epitope across the lateral face of a neuramindase (NA) dimer.

The subject technology may offer an alternative to therapeutic NA inhibitors currently available. CD6 is a potent monoclonal antibody against N1 subtypes of NA that inhibits the enzymatic activity of the NA protein, including NA variants resistant to NA inhibitors. In a murine model of infection, a single dose of antibody was protective against lethal challenge with H1N1 influenza virus. The CD6 antibody can potentially be used in combination with other antibodies in an antibody "cocktail" or in conjunction with other therapeutic agents. Additionally, this unique anti-NA antibody may be useful in combination with known neutralizing anti-hemagglutinin (HA) antibodies.

Potential Commercial Applications:

- Prophylactic and therapeutic against influenza virus infections;
- Diagnostic tests for influenza virus infections; and
- Reagent to measure the potency of H1N1 NA in influenza virus vaccines.

Competitive Advantages:

- Monoclonal antibody demonstrated to be effective against circulating H1N1 influenza viruses;
- Monoclonal antibody binds a novel, conserved epitope spanning NA dimers; and

- Monoclonal antibody is well-suited for an antibody cocktail that includes anti-HA antibodies.

Development Stage: Early state; In vitro data available; In vivo data available (animal).

Inventors: Hongquan Wan (FDA); Maryna Eichelberger (FDA); Hua Yang (CDC); James Stevens (CDC); David Shore (CDC); and Rebecca Garten (CDC).

Publication: Wan, H., H. Yang, D. A. Shore, R. J. Garten, L. Couzens, J. Gao, L. Jiang, P. J. Carney, J. Villanueva, J. Stevens, and M. C. Eichelberger. "Structural Characterization of a Protective Epitope Spanning A(H1N1)pdm09 Influenza Virus Neuraminidase Monomers." 6:6114, Nature Communications, 2015.

Intellectual Property: HHS Reference No. E-005-2015/0 -- U.S. Provisional Patent Application No. 62/088,388 filed December 5, 2014.

Licensing and Collaborative Research Opportunity: The invention is owned by an Agency of the U.S. Government and is available for licensing in accordance with 35 U.S.C. 209 and 37 CFR part 404.

The Food and Drug Administration is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Parties interested in licensing or collaborative research activities for this technology should contact William Ronnenberg (see FOR FURTHER INFORMATION CONTACT).

Dated: February 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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