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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: Wade Green at 301-761-7505, or *wade.green@nih.gov*. Information may be obtained by communicating with 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Broadly neutralizing influenza hemagglutinin stem-directed antibodies

Description of Technology:

In 2023, the World Health Organization (WHO) reported roughly 3 to 5 million cases of severe influenza worldwide, resulting in approximately 290,000 to 650,000 deaths. Given the high disease burden, the needs for both prophylactic and therapeutic influenza strategies remain significant. However, current treatments for influenza are susceptible to resistance and are useful for only a limited post-infection period.

The highly conserved epitopes in the stem region of the influenza hemagglutinin (HA) protein are ideal targets for new vaccines, as they elicit broadly neutralizing antibodies. In light of this, researchers at the National Institute of Allergy and Infectious Diseases (NIAID) cloned and expressed HA stem-specific monoclonal antibodies (mAbs) from B cells isolated from human participants in influenza vaccine clinical trials. Four mAbs exhibited particularly potent neutralizing profiles against H1N1 strains, three exhibited very strong neutralization profiles against H3N2 strains, and two exhibited a good neutralization profile across all subtypes tested. These mAbs may help to substantially reduce global influenza disease burden given their potential to become effective therapeutic and prophylactic agents against a broad range of H1N1 and H3N2 influenza strains.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Prophylactic or therapeutic strategies against influenza infection

Competitive Advantages:

- Greater neutralization potency against H1N1 and H3N2 strains than observed for other high-profile candidates tested in phase II clinical trials

Developmental Stage: Preclinical

Publications:

- Andrews SF, et al. An influenza H1 hemagglutinin stem-only immunogen elicits a broadly cross-reactive B cell response in humans. *Sci. Transl. Med.* 2023;15:eade4976.

- Mantus GE, et al. Vaccination with different group 2 influenza subtypes alters epitope targeting and breadth of hemagglutinin stem–specific human B cells. *Sci. Transl. Med*. 2025;17:eadr8373.

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Intellectual Property: HHS Reference No. E-026-2024; Provisional Patent Application No.: 63/605,374, filed on December 1, 2023, and PCT Patent Application No. PCT/US2024/057131, filed on November 22, 2024.

Licensing Contact: To license this technology, please contact Wade Green at 301-761-7505, or *wade.green@nih.gov,* and reference E-026-2024.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. For collaboration opportunities, please contact Wade Green at 301-761-7505, or *wade.green@nih.gov*, and reference E-026-2024.

Dated: June 9, 2025.

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