



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: Dawn Taylor-Mulneix at 301-767-5189 or dawn.taylor-mulneix@nih.gov. Licensing 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.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:

Human monoclonal and bispecific antibodies targeting SARS-CoV-2 coronavirus.

Description of Technology:

SARS-CoV-2 is a virus of the Coronavirus family that has emerged as a major public health concern. The first cases of SARS-CoV-2 were reported in China and rapidly spread worldwide leading to a global pandemic. The highest morbidity and mortality have been reported in the elderly and immunocompromised. Antibody therapeutics have great importance for advanced cases of SARS-CoV-2 where a vaccine would not be effective and may be more effective than a vaccine in certain high-risk populations.

Scientists at NIAID have developed recombinant monoclonal antibodies that are effective *in vitro* and *in vivo* at neutralizing SARS-CoV-2. Based on whether they are mono-specific or bi-specific and where they bind to the SARS-CoV-2 virus, these antibodies can be subdivided into four groups that target (A) the receptor-binding-domain (RBD) of the SARS-COV-2 spike protein, (B) the N-terminal domain (NTD) of the SARS-COV-2 spike protein, (C) dual locations on the RBD, or (D) both the RBD and NTD. Crucially, these antibodies effectively neutralize the emerging B.1.1.7 and B.1.351 SARS-CoV-2 variants of concern.

These recombinant monoclonal antibodies can be used alone, in combination, or with other therapeutics for the treatment of SARS-COV-2. In addition to their potential as therapeutics, these antibodies against SARS-CoV-2 can be used as prophylactics and in assay development. They can contribute to the surveillance, diagnosis, and prevention of SARS-COV-2. Furthermore, the specific antibody sequences and targets will inform vaccine development and establishment of long-term immunity.

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:

- Prophylaxis or therapeutics against SARS-CoV-2.
- Diagnostics and surveillance of SARS-CoV-2.
- Vaccine research.

Competitive Advantages:

- Potent neutralizing activity against SARS-CoV-2, including against B.1.1.7 and B.1.351 variants.
- Prophylactic usage against SARS-CoV-2 in normal or high-risk populations.

- Therapeutic treatment, alone or in combination, in patients with SARS-CoV-2 infection.
- Assay development for surveillance, diagnostic, and prevention measures.
- Identification of vaccine candidates which elicit protective antibodies against SARS-CoV-2 infections.

Development Stage:

- Pre-clinical

Inventors: Joshua Tan, Ph.D., Peter Crompton, M.D., Hyeseon Cho, Ph.D., Mary Peterson, Kristina Kay Gonzales-Wartz, Ph.D., all of NIAID.

Publications: Cho, Hyeseon, et. al. “Ultrapotent bispecific antibodies neutralize emerging SARS-CoV-2 variants.” bioRxiv 2021.04.01.437942;

Intellectual Property: HHS Reference No. E-030-2021-0; US provisional application No. 63/127,077 filed on December 17, 2020.

Licensing Contact: To license this technology, please contact Dawn Taylor-Mulneix 301-767-5189 or dawn.taylor-mulneix@nih.gov, and reference E-030-2021-0.

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 Dawn Taylor-Mulneix at 301-767-5189 or dawn.taylor-mulneix@nih.gov.

Dated: April 7, 2021.

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