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.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Biobehavioral and Behavioral Sciences Subcommittee.

Date: June 28, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NICHD Offices, 6710B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Clay Mash, Ph.D., Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2131A, Bethesda, MD 20892, (301) 496–6866, *mashc@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: April 12, 2021.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Instrumentation and Systems Development Study Section.

Date: June 17–18, 2021.