

2. Effective Time Period, Section XII, Add to the End of the Section:

Liability protections for Qualified Persons under sections V(f) and V(d) of the declaration begin on February 8, 2021 and last through October 1, 2024.

Authority: 42 U.S.C. 247d-6d.

Norris Cochran,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2021-03106 Filed 2-11-21; 4:15 pm]

BILLING CODE 4150-37-P

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: Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Epstein-Barr Virus Antibody That Blocks Fusion And Neutralizes Virus Infection of B Cells

Description of Technology

Epstein-Barr virus (EBV) is the most common cause of infectious mononucleosis and is associated with nearly 200,000 cancers and 140,000 deaths each year. EBV-associated cancers include Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt B cell lymphoma, and EBV post-transplant lymphoproliferative disease. The latent

reservoir for EBV in the body is the B lymphocyte. Thus, blocking B cell infection is important for reducing EBV-related disease.

EBV can infect both B cells and epithelial cells; however, the method of entry differs between these two cell types. To initiate B cell infection, EBV glycoprotein 350 (gp350) binds to complement receptor 2 (CR2; also known as CD21), followed by binding of glycoprotein 42 (gp42) to HLA class II molecules, which triggers fusion of EBV with the B cell, allowing virus entry into the cell. Fusion also requires the EBV proteins gH/gL, which are found complexed with gp42 as a heterotrimer, and gB. Infection of epithelial cells is initiated by the binding of the EBV protein BMRF2 to cellular integrins, followed by binding of gH/gL to ephrin receptor A2 and integrins, which triggers fusion by EBV gB.

Monoclonal antibodies that specifically bind EBV gp42 are described by this invention. The gp42-specific antibodies are capable of neutralizing EBV infection and inhibiting fusion of EBV with B cells. The monoclonal antibodies can be used for the treatment or prophylaxis of EBV infection, prevention of EBV-associated disease or infection in immunocompromised subjects, diagnosis of EBV infection, and detection of EBV in a biological sample.

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

- Viral diagnostics
- Viral therapeutics
- Viral prophylaxis
- Vaccine research

Competitive Advantages

- Ease of manufacture
- Strongly neutralizing antibodies
- Alternative to EBV vaccines

Development Stage

- In vivo data assessment (animal)
- Inventors:* Jeffrey Cohen (NIAID), Wei Bu (NIAID), Nathan Board (NIAID), Kennichi Dowdell (NIAID).

Intellectual Property: HHS Reference No. E-020-2020-0—U.S. Provisional Application No. 62/979,070, filed February 20, 2020.

Licensing Contact: Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

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 for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Dated: January 28, 2021.

Surekha Vathyam,

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

[FR Doc. 2021-03045 Filed 2-12-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Renal RC2 Applications.

Date: March 19, 2021.

Time: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, 6707 Democracy Boulevard, Room 7015, Bethesda, MD 20892-2542, 301-594-4721, ryan.morris@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 9, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-03015 Filed 2-12-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

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

The meetings 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS-NIH-CDC-SBIR PHS 2021-1 Phase I: Pediatric Formulations of Select Second Line Drugs for Treating Tuberculosis (Topic 97).

Date: February 22, 2021.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Mario Cerritelli, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892, 240-669-5199, cerritem@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS-NIH-CDC-SBIR PHS 2021-1 Phase I: Pediatric Formulations of Select Second Line Drugs for Treating Tuberculosis (Topic 96).

Date: February 24, 2021.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Mario Cerritelli, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892, 240-669-5199, cerritem@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS-NIH-CDC-SBIR PHS 2021-1 Phase II: Pediatric Formulations of Select Second Line Drugs for Treating Tuberculosis (Topic 97).

Date: February 24, 2021.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Mario Cerritelli, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892, 240-669-5199, cerritem@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 9, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-03016 Filed 2-12-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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FOR FURTHER INFORMATION CONTACT:

Chris Kornak at 240-627-3705 or Chris.Kornak@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:

Replication-Competent Adenovirus Type 4 SARS-CoV-2 Vaccines and Their Use

Description of Technology

NIAID has produced recombinant adenovirus type 4 (Ad4), SARS-CoV-2 spike, vectors for administration to humans. These recombinant vaccines permit rapid development of high levels of neutralizing antibodies to SARS-CoV-2 in experimental animals. This vaccine is designed to improve the durability of the immune response by inducing mucosal and systemic immunity. Further, this system should be incredibly simple and efficient when producing vaccine at scale. 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

- Vaccine composition(s)

Competitive Advantages

- Stimulates a durable immune response;
- Induction of mucosal and systemic immunity;
- Potential for transmission interruption;
- Intranasal administration minimizes the impact of pre-existing immunity;
- Notable improvement for manufacturing yield and cost, ease of administration, and distribution as compared to current candidates.

Inventor: Mark Connors, M.D. (NIAID)
Publications: Matsuda et al. Journal of Clinical Investigation, 2021. (<https://doi.org/10.1172/JCI140794>). Matsuda et al., Science Immunology 2019 (<https://doi.org/10.1126/sciimmunol.aau2710>).

Intellectual Property: HHS Reference E-055-2021; Application No. 63/138,221.

Licensing Contact: To license this technology, please contact Chris Kornak at chris.kornak@nih.gov.