

immunotherapy using autologous human T cells transduced with lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets CD33 (comprised of the CD33-binding domain referenced as Hu195 or hP67.6 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of CD33-expressing cancers. For clarity, “CD33-specific logic-gated CAR-based immunotherapy” means therapies where the CAR-expressing T cells recognize CD33 and are engineered to respond to one or more additional antigens (but not necessarily all of the antigens).

2. The development of a CD33-specific logic-gated CAR-based immunotherapy using allogeneic human NK cells transduced with retroviral vectors, including but not limited to lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets CD33 (comprised of the CD33-binding domain referenced as Hu195 or hP67.6 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of CD33-expressing cancers. For clarity, “CD33-specific logic-gated CAR-based immunotherapy” means therapies where the CAR-expressing NK cells recognize CD33 and are engineered to respond to one or more additional antigens (but not necessarily all of the antigens).

These technologies disclose therapies to treat AML by utilizing CARs that recognize AML cells through a binder for CD33. The CD33 binders are known as Hu195 or hP67.6. CD33 is a well validated immunotherapeutic target that is expressed on the surface of malignant cells, most notably on the surface of acute myelogenous leukemia (AML) blasts.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business

confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 7, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

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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: Production of Adjuvants Mimics (Topic 093) (For SBIRs Phase I)

Date: February 1, 2021.

Time: 11:00 a.m. to 1:30 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 3F52, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Maggie A. Morris Fears, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52, Rockville, MD 20852, 301-761-5444, maggie.morrisfears@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: Adjuvant Discovery for Vaccines and for Autoimmune and Allergic Disease (Topic 092) (For SBIRs Phase I).

Date: February 1, 2021.

Time: 1:30 p.m. to 2:30 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 3F52, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Maggie A. Morris Fears, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52, Rockville, MD 20852, 301-761-5444, maggie.morrisfears@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: Adjuvant Discovery for Vaccines and for Autoimmune and Allergic Disease (Topic 092) (For SBIRs Phase II).

Date: February 1, 2021.

Time: 2:30 p.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 3F52, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Maggie A. Morris Fears, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52, Rockville, MD 20852, 301-761-5444, maggie.morrisfears@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: January 8, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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.