

FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that OTARMENI (lunsotogene parvec-cwha), manufactured by Regeneron Pharmaceuticals, Inc., meets the criteria for a priority review voucher. OTARMENI (lunsotogene parvec-cwha) is indicated for the treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the *OTOF* gene, preserved outer hair cell function, and no prior cochlear implant in the same ear.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs>. For further information about OTARMENI (lunsotogene parvec-cwha), go to the Center for Biologics Evaluation and Research's Approved Cellular and Gene Therapy Products website at <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-08913 Filed 5-5-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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 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: Center for Scientific Review Special Emphasis Panel; Psychosocial Influences on Healthy Development.

Date: June 4, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kimberly L. Houston, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-4902, Kimberly.Houston@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Par Panel; Enhancing Mechanistic Research on Precision Probiotic Therapies.

Date: June 4, 2026.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Dayadevi Jirage, Ph.D. Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4422, Bethesda, MD 20892, (301) 867-5309, jiragedb@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Training: Career Development

Date: June 4, 2026.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Delia Tang, MD, Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (240) 276-6456, tangd@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Clinical Neuroimmunology and Brain Tumors.

Date: June 4, 2026.

Time: 4:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Dario Dieguez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-3101, dario.dieguez@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Skeletal Development, Repair and Regeneration.

Date: June 9, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vanessa Dawn Sherck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 801C, Bethesda, MD 20892, (301) 594-3218, sherkv2@csr.nih.gov.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Basic Cancer Immunobiology Study Section.

Date: June 9-10, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301-402-4788, sarita.sastry@nih.gov.

Name of Committee: Applied Immunology and Disease Control Integrated Review Group; Interspecies Microbial Interactions and Infections Study Section.

Date: June 10, 2026.

Time: 10:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Irene Ramos Lopez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892, (301) 480-4891, irene.ramoslopez@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: Translational Cancer Research SPORE P50.

Date: June 11, 2026.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Amr M. Ghaleb, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 812, Bethesda, MD 20892, (301) 443-5851, amr.ghaleb@nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Prokaryotic Cell and Molecular Biology Study Section.

Date: June 11, 2026.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.
Contact Person: Rebecca Catherine Burgess, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-8034, rebecca.burgess@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Population Dynamics and Health.

Date: June 11, 2026.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770 Bethesda, MD 20892, (301) 435-1712, ryansj@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 1, 2026.

Margaret N. Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-08782 Filed 5-5-26; 8:45 am]

BILLING CODE 4167-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Integrative Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Complementary and Integrative Health.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Once available, the open session meeting link can be accessed through the Institute's/Center's home page: <https://nccih.nih.gov/about/nccih> and through the NIH Videocast web page <https://videocast.nih.gov/>.

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 Advisory Council for Complementary and Integrative Health.

Date: June 29, 2026.

Closed: 10:00 a.m. to 11:30 p.m..

Agenda: To review and evaluate grant applications.

Address: National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, Virtual Meeting.

Open: 12:30 p.m. to 5:00 p.m.

Agenda: Reports and Updates about Recent and Ongoing NCCIH Led or Involved Activities by NCCIH staff and its Director.

Address: National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, Virtual Meeting.

Contact Person: Martina Schmidt, Ph.D., Director, Division of Extramural Activities, National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, (301) 594-3456, schmidma@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should be less than 700 words in length, and should include the name, email address, telephone number and when applicable, the business or professional affiliation of the interested person. Any member of the public may submit written comments no later than June 15th, 2026 (14 days before the council meeting).

Information is also available on the Institute's/Center's home page: <https://nccih.nih.gov/about/nccih>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: May 01, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-08783 Filed 5-5-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Engineered Cell Therapies for the Treatment of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of

Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the patents and patent applications listed in the Supplementary Information section of this notice to OncoVanta Therapeutics, Inc. ("OncoVanta"), a company located in Hagerstown, Maryland, the United States of America.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before May 21, 2026 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240) 276-5484; Email: andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 63/185,805 filed May 7, 2021, entitled "T Cell Receptors Recognizing C135Y, R175H or M237I Mutation in P53" [HHS Reference No. E-101-2021-0-US-01];

2. PCT Application No. PCT/US2022/028066 filed May 6, 2022, entitled "T Cell Receptors Recognizing C135Y, R175H or M237I Mutation in P53" [HHS Reference No. E-101-2021-0-PCT-02];

3. Canadian Patent Application No. 3217263 filed October 30, 2023, entitled "T Cell Receptors Recognizing C135Y, R175H or M237I Mutation in P53" [HHS Reference No. E-101-2021-0-CA-03];

4. Japanese Patent Application No. 2023-568469 filed November 6, 2023, entitled "T Cell Receptors Recognizing C135Y, R175H or M237I Mutation in P53" [HHS Reference No. E-101-2021-0-JP-02];

5. United States Patent Application No. 18/289,596 filed November 6, 2023, entitled "T Cell Receptors Recognizing C135Y, R175H or M237I Mutation in P53" [HHS Reference No. E-101-2021-0-US-07];

6. European Patent Application No. 22726335.7 filed November 22, 2023, entitled "T Cell Receptors Recognizing C135Y, R175H or M237I Mutation in P53" [HHS Reference No. E-101-2021-0-EP-08];

7. South Korean Patent Application No. 10-2023-7041691 filed December 1, 2023, entitled "T Cell Receptors Recognizing C135Y, R175H or M237I Mutation in P53" [HHS Reference No. E-101-2021-0-KR-06];