

Background on the Task Force: The Task Force is an independent, nonfederal panel whose members are appointed by the CDC Director. Task Force members represent a broad range of research, practice, and policy expertise in prevention, wellness, health promotion, and public health. The Task Force was convened in 1996 by the Department of Health and Human Services (HHS) to identify community preventive programs, services, and policies that increase healthy longevity, save lives and dollars, and improve Americans' quality of life. CDC is mandated to provide ongoing administrative, research, and technical support for the operations of the Task Force. During its meetings, the Task Force considers the findings of systematic reviews on existing research and practice-based evidence and issues recommendations. Task Force recommendations are not mandates for compliance or spending. Instead, they provide information about evidence-based options that decision makers and stakeholders can consider when they are determining what best meet the specific needs, preferences, available resources, and constraints of their jurisdictions and constituents. The Task Force's recommendations, along with the systematic reviews of the evidence on which they are based, are compiled in the *Guide to Community Preventive Services (The Community Guide)*.

Matters proposed for discussion: Cardiovascular Disease Prevention (Mobile Health Interventions for Cardiovascular Disease Prevention); Diabetes Prevention and Control (Lifestyle Interventions to Reduce Risk of Gestational Diabetes); Nutrition (Gardening-Based Interventions to Increase Fruit and Vegetable Intake); Obesity Prevention and Control (School-based Diet and Physical Activity Interventions); and Women's Health (Primary Prevention of Intimate Partner Violence and Sexual Violence Among Youth). The agenda is subject to change without notice.

Roybal Campus Security Guidelines: The Edward R. Roybal Campus is the headquarters of the CDC and is located at 1600 Clifton Road NE., Atlanta, Georgia. The meeting is being held in a Federal government building; therefore, Federal security measures are applicable.

All meeting attendees must register by the dates outlined under *Meeting Accessibility*. In planning your arrival time, please take into account the need to park and clear security. All visitors must enter the Edward R. Roybal Campus through the front entrance on Clifton Road. Vehicles may be searched,

and the guard force will then direct visitors to the designated parking area. Upon arrival at the facility, visitors must present government-issued photo identification (e.g., a valid federal identification badge, state driver's license, state non-driver's identification card, or passport). Non-U.S. citizens must complete the required security paperwork prior to the meeting date and must present a valid passport, visa, Permanent Resident Card, or other type of work authorization document upon arrival at the facility. All persons entering the building must pass through a metal detector. CDC Security personnel will issue a visitor's ID badge at the entrance to Building 19. Visitors may receive an escort to the meeting room. All items brought to HHS/CDC are subject to inspection.

Dated: September 6, 2017.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2017-19203 Filed 9-8-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4851]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. Members will participate via teleconference.

DATES: The meeting will be held on October 4, 2017, from 1 p.m. to 4:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. For those unable to attend in person, the meeting will also be webcast and will be available at the following link: <https://collaboration.fda.gov/cbervrpbac2017>. Answers to commonly asked questions including information regarding special

accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

Serina Hunter-Thomas or Rosanna Harvey, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993-0002, 240-402-5771 serina.hunter-thomas@fda.hhs.gov and 240-402-8072, rosanna.harvey@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On October 4, 2017, the VRBPAC will meet in an open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2018 southern hemisphere influenza season. FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 27, 2017. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief

statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 19, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 20, 2017.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 5, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-19129 Filed 9-8-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0809]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the FD&C Act),

as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that KYMRIA (tisagenlecleucel), manufactured by Novartis Pharmaceuticals Corporation, meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Gretchen Oppen, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that KYMRIA (tisagenlecleucel), manufactured by Novartis Pharmaceuticals Corporation, meets the criteria for a priority review voucher. KYMRIA (tisagenlecleucel) is indicated for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.

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/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about KYMRIA (tisagenlecleucel), go to the Center for Biologics Evaluation and Research cellular and gene therapy products Web site at <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/default.htm>.

Dated: September 5, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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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: Dr. Vince Contreras, 240-669-2823; Vince.Contreras@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.

Broadly Neutralizing Antibodies Against HIV-1 Directed to the CD4 Binding Site of HIV Envelope Protein

Description of Technology

Inhibiting the ability of HIV-1, the virus that causes AIDS, to infect cells is one approach to both prevention and treatment of HIV. Scientists at the NIAID Vaccine Research Center have isolated and characterized neutralizing antibodies (VRC01, 02, 03, and 07) that bind to the CD4 binding site of HIV-1 envelope glycoprotein gp120. These human monoclonal antibodies can potentially be used as a therapeutic to: (1) Treat an HIV infection, (2) decrease and prevent HIV-transmission from mother to infant, and (3) be effectively combined with anti-retroviral drug therapy. Additionally, the antibodies can be used for detection of HIV-1 infection in biological samples, including body fluids; and tissues from biopsies, autopsies, and pathology specimens.

VRC01 has been tested in several phase I clinical trials for safety and pharmacokinetics in infants, adults, and