FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
79th Meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC)
July 30, 2026
DRAFT AGENDA

The committee will meet in open session to discuss and make recommendations on Biologics License Application (BLA) 125827, from Replimune, Inc., for vusolimogene oderparepvec submitted for (use) in combination with nivolumab for the treatment of adult patients with advanced melanoma who have previously received an anti-PD-1 containing regimen.

Time EDT	Presentation/Presenter
9:30 a.m.	**Opening Remarks: Call to Order and Welcome (5 min)** Evan Snyder, MD, PhD, FAAP, Acting Chairperson, CTGTAC **Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (10 min)** LCDR Cicely Reese, PharmD, Designated Federal Officer CBER, FDA
9:45 a.m.	**FDA Welcome (5 min)** **Karim Mikhail, BPharm, MSc** Acting Director, CBER Acting Director, Office of Therapeutic Products (OTP) CBER, FDA
9:50 a.m.	**FDA Introduction and Regulatory Overview (20 min including Q & A)** **Introductory Remarks and Regulatory Background of BLA** **Sundeep Agrawal, MD** Associate Director of Oncology Clinical Programs Oncology Center of Excellence **Q & A (5 min)**
10:10 a.m.	**Applicant Presentations (70 min including Q & A)** **Introduction** **Sushil Patel, PhD** CEO, Replimune Inc. **Regulatory Overview** **Kari Jeschke, MA** SVP, Regulatory Affairs, Replimune Inc. **MoA / Biologic Plausibility** **Kevin Harrington, MD, PhD, FRCP, FRCR, FRSB** Professor of Biological Cancer Therapies Institute of Cancer Research

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	Disease Background/Unmet Need **Michael Wong, MD, PhD, FRCPc** Clinician, IGNYTE Study Advisory Board Former Physician in Chief, Roswell Park Cancer Center **RP1 Clinical Benefit / Risk Profile** **Kostas Xynos, MD, PhD, MBA** Chief Medical Officer, Replimune Inc. **Clinical Perspective** **Mo Milhem, MBBS** Professor of Internal Medicine Division of Hematology and Oncology, University of Iowa **Q & A (15 min)**
11:20 a.m.	**LUNCH (45 min)**
12:05 p.m.	**Open Public Hearing (90 min)**
1:35 p.m.	**BREAK (30 min)**
2:05 p.m.	**FDA Presentation (70 min including Q & A)** **BLA 125827** **Katherine Barnett, MD** Acting Branch Chief, Oncology Branch 2 Division of Clinical Evaluation Oncology Office of Clinical Evaluation OTP, CBER, FDA **Q & A (15 min)**
3:15 p.m.	**Committee Discussion (90 min)** Discussion and Voting Questions
4:45 p.m.	**Closing Remarks (5 min)** **Megha Kaushal, MD, MSc** Acting Deputy Director OTP, CBER, FDA
4:50 p.m.	**ADJOURNMENT**