

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 12, 2017

DRAFT AGENDA

The committee will discuss biologics license application (BLA) 125646 for tisagenlecleucel-T suspension for intravenous use. The application was submitted by Novartis Pharmaceuticals Corp. The proposed indication (use) for this product is for the treatment of pediatric and young adult patients 3 to 25 years of age with relapsed/refractory B-cell acute lymphoblastic leukemia (ALL).

8:00 a.m.	Call to Order and Introduction of Committee	Bruce J. Roth, MD Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	Jennifer Shepherd, RPh Acting Designated Federal Officer, ODAC
8:10 a.m.	Introductory Remarks	Wilson W. Bryan, MD Director Office of Tissues and Advanced Therapies (OTAT) Center for Biologics Evaluation and Research (CBER) FDA
8:15 a.m.	APPLICANT PRESENTATIONS	Novartis Pharmaceuticals Corp.
	Introduction	Samit Hirawat, MD Head, Oncology Global Development Unit Novartis Pharmaceuticals Corp.
	Manufacturing	Spencer Fisk, BSc Head, Cell & Gene Technical Development & Manufacturing Novartis Pharmaceuticals Corp.
	Lentiviral Vector	James Miskin, PhD Chief Technical Officer Oxford Biomedica (UK) Ltd.
	Correlations Between Product Attributes and Clinical Outcomes	David Lebwohl, MD CAR-T Franchise Global Program Head Novartis Pharmaceuticals Corp.
9:00 a.m.	FDA PRESENTATION	
	Tisagenlecleucel CMC presentation	Xiaobin Victor Lu, PhD Chemistry, Manufacturing & Controls (CMC) Reviewer Gene Therapies Branch (GTB) Division of Cellular & Gene Therapies (DCGT) OTAT, CBER, FDA

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DRAFT AGENDA (cont.)

10:00 a.m. Clarifying Questions to the Presenters

10:15 a.m. **BREAK**

10:30 a.m. **OPEN PUBLIC HEARING**

11:00 a.m. Questions to the Committee/Committee Discussion

12:00 p.m. **LUNCH**

1:00 p.m. **APPLICANT PRESENTATIONS**

Novartis Pharmaceuticals Corp.

Unmet Need

Stephen P. Hunger, MD
Children's Hospital of Philadelphia

Efficacy

Samit Hirawat, MD

Safety

David Lebwohl, MD

Clinical Perspective

Stephan Grupp, MD, PhD
Children's Hospital of Philadelphia

Conclusion

David Lebwohl, MD

1:45 p.m. **FDA PRESENTATION**

BLA 125646 Tisagenlecleucel

Maura O'Leary, MD
Medical Officer, Team Leader
Clinical Hematology Branch (CHB)
Division of Clinical Evaluation & Pharmacology/Toxicology
(DCEPT)
OTAT, CBER, FDA

2:30 p.m. Clarifying Questions to the Presenters

2:45 p.m. **BREAK**

3:00 p.m. **OPEN PUBLIC HEARING**

3:30 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**