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

AGENDA

The committee will discuss biologics license application (BLA) 125646 for tisagenlecleucel 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.
	Unmet Need	**Stephen P. Hunger, MD** Children's Hospital of Philadelphia
	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.

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AGENDA (cont.)

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
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.**
	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**	