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

Oncologic Drugs Advisory Committee (ODAC) Meeting
June 24, 2021

DRAFT AGENDA

The committee will discuss Biologics License Application (BLA) 761209 for retifanlimab injection, submitted by Incyte Corporation. The proposed indication (use) for this product is for the treatment of adult patients with locally advanced or metastatic squamous carcinoma of the anal canal (SCAC) who have progressed on or who are intolerant of platinum-based chemotherapy.

10:30 a.m.	Call to Order	**Philip C. Hoffman, MD** Chairperson, ODAC
10:35 a.m.	Introduction of Committee and Conflict of Interest Statement	**She-Chia Chen, PharmD** Designated Federal Officer, ODAC
10:40 a.m.	FDA Introductory Comments	**Sandra Casak, MD** Team Leader (Acting) Division of Oncology 3 (DO3) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
10:50 a.m.	**APPLICANT PRESENTATIONS**	**Incyte Corporation**
	Introduction	**Michael J. McGraw, PharmD, MS** Executive Director, Global Regulatory Affairs Incyte Corporation
	Unmet Need	**Marwan Fakih, MD** Professor, Medical Oncology and Therapeutics Research Judy and Bernard Briskin Distinguished Director in Clinical Research City of Hope Comprehensive Cancer Center
	Efficacy and Safety	**Mark Cornfeld, MD, MPH** Vice President, Immuno-Oncology Drug Development Incyte Corporation
	Clinical Perspective	**Marwan Fakih, MD**
	Benefit-Risk	**Mark Cornfeld, MD, MPH**

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DRAFT AGENDA (cont.)

11:35 a.m.	**FDA PRESENTATION**	
	BLA 761209 - Retifanlimab	**May Tun Saung, MD** Clinical Reviewer DO3, OOD, OND, CDER, FDA
12:10 p.m.	Clarifying Questions to Presenters	
12:40 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Questions to the Committee/Committee Discussion	
2:45 p.m.	**ADJOURNMENT**	