

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
February 9, 2023

AGENDA

The committee will discuss investigational new drug application (IND) 157775, for dostarlimab-gxly for injection, submitted by GlaxoSmithKline LLC. The proposed indication (use) for this product is as a single agent for the treatment of patients with locally advanced, treatment-naïve mismatch repair deficiency/microsatellite instability-high rectal cancer. FDA would like to obtain the committee's input on the following: (1) the adequacy of the proposed trial(s) to evaluate the benefits and risks of dostarlimab for the proposed indication, including trial design, study population, clinical endpoint, and patient followup; and (2) the adequacy of the proposed data package to permit an assessment of the benefits and risks of dostarlimab for the proposed indication.

11:00 a.m.	Call to Order	Jorge Garcia, MD, FACP Chairperson, ODAC
11:05 a.m.	Introduction of Committee and Conflict of Interest Statement	Rhea Bhatt Acting Designated Federal Officer, ODAC
11:10 a.m.	FDA Opening Remarks	‘Lola Fashoyin-Aje, MD, MPH Deputy Director Division of Oncology Products 3 (DO3) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
11:30 a.m.	APPLICANT PRESENTATIONS	GlaxoSmithKline LLC. (GSK)
	Introduction	Ivan Diaz-Padilla, MD, PhD Vice President, Clinical Development Head, Immuno-Oncology GSK
	Standard of Care	Andrea Cercek, MD Head, Colorectal Cancer Section Co-Director Center for Young Onset Colorectal and GI Cancers Memorial Sloan Kettering Cancer Center (MSKCC)
	Scientific Rationale Supporting cCR12	J. Joshua Smith, MD, PhD, FACS Surgical Oncologist and Associate Attending Surgeon MSKCC

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

MSKCC Study Design and Interim Results **Andrea Cercek, MD**
Head, Colorectal Cancer Section, Co-Director
Center for Young Onset Colorectal and GI Cancers
MSKCC

GSK Design of Phase 2 Study **Ivan Diaz-Padilla, MD, PhD**

GSK Commitment to Accelerated
Approval **Hesham Abdullah, MD, MSc**
Senior Vice President, Global Head of Oncology
Development, GSK

Moderator for Q&A **Gordana Vlahovic, MD, MHS**
Vice President, Medicines Development Lead
GSK

12:05 p.m. **GUEST SPEAKER PRESENTATION**

Overview of the Management of Stage II-
III Rectal Cancer **Kimmie Ng, MD, MPH**
Associate Chief, Division of Gastrointestinal
Oncology
Associate Professor of Medicine, Harvard Medical
School
Director, Young-Onset Colorectal Cancer Center
Co-Director, Colon and Rectal Cancer Center
Director of Translational Research in
Gastrointestinal Cancer
Dana-Farber Cancer Institute

12:40 p.m. **FDA PRESENTATION**

Dostarlimab Development in
dMMR/MSI-H Locally Advanced Rectal
Cancer **Sandra Casak, MD**
Clinical Team Leader
Gastrointestinal Cancers Team
DO3, OOD, OND, CDER, FDA

1:15 p.m. Clarifying Questions to Presenters

2:15 p.m. **BREAK**

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AGENDA (cont.)

- 2:45 p.m. **OPEN PUBLIC HEARING**
- 3:45 p.m. Questions to the Committee/Committee Discussion
- 5:30 p.m. **ADJOURNMENT**