

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

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

DRAFT 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**

Introduction

GlaxoSmithKline LLC. (GSK)

Standard of Care

Ivan Diaz-Padilla, MD, PhD
Vice President, Clinical Development Head,
Immuno-Oncology
GSK

Scientific Rationale Supporting cCR12

Andrea Cerck, MD
Head, Colorectal Cancer Section
Co-Director Center for Young Onset Colorectal and
GI Cancers
Memorial Sloan Kettering Cancer Center (MSKCC)

J. Joshua Smith, MD, PhD, FACS
Surgical Oncologist and Associate Attending
Surgeon
MSKCC

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

MSKCC Study Design and Interim Results

Andrea Cersek, 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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DRAFT AGENDA (cont.)

2:45 p.m. **OPEN PUBLIC HEARING**

3:45 p.m. Questions to the Committee/Committee Discussion

5:30 p.m. **ADJOURNMENT**