

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
April 27-29, 2021

AGENDA

The committee will hear updates on certain supplemental biologics license applications (sBLAs) approved under 21 CFR 601.40 (subpart E, accelerated approval regulations) with confirmatory trial(s) that have not verified clinical benefit. These updates will provide information on: (1) the status and results of confirmatory clinical studies for a given indication; and (2) any ongoing and planned trials. Confirmatory studies are post-marketing studies to verify and describe the clinical benefit of a drug after it receives accelerated approval. Based on the updates provided, the committee will have a general discussion focused on next steps for each product including whether the indications should remain on the market while additional trial(s) are conducted.

On April 27, 2021, the committee will receive updates on the following product: BLA 761034/S-018, for TECENTRIQ (atezolizumab), submitted by Genentech, Inc., indicated in combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells (IC) of any intensity covering $\geq 1\%$ of the tumor area), as determined by an FDA-approved test.

1:00 p.m.	Call to Order	Philip C. Hoffman, MD Chairperson, ODAC
1:05 p.m.	Introduction of Committee and Conflict of Interest Statement	Joyce Yu, PharmD Acting Designated Federal Officer, ODAC
1:10 p.m.	FDA Introductory Comments on Accelerated Approval for Oncology Drug Products: Regulatory Overview	Julia Beaver, MD Chief of Medical Oncology Oncology Center of Excellence (OCE) Deputy Director (acting) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
1:20 p.m.	APPLICANT PRESENTATIONS	Genentech, Inc.
	Introduction	Charles Fuchs, MD Senior Vice President, Product Development Oncology Genentech, a Member of the Roche Group
	Sponsor's Position on Maintaining the Accelerated Approval for Atezolizumab (Tecentriq®) in Combination with nab-Paclitaxel in PD-L1+ Metastatic Triple-Negative Breast Cancer	Stephen Y. Chui, MD Group Medical Director, Product Development Oncology Genentech

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April 27-29, 2021

AGENDA (cont.)

1:50 p.m. **FDA PRESENTATION**

Atezolizumab + Nab-Paclitaxel
PDL-1 + metastatic triple negative breast
cancer

Laleh Amiri-Kordestani, MD
Director
Division of Oncology 1 (DO1)
OOD, OND, CDER, FDA

2:10 p.m. Clarifying Questions to Presenters

2:40 p.m. **BREAK**

2:55 p.m. **OPEN PUBLIC HEARING**

3:15 p.m. Questions to the Committee/Committee
Discussion

3:45 p.m. **ADJOURNMENT**

**FOOD AND DRUG ADMINISTRATION (FDA)
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Oncologic Drugs Advisory Committee (ODAC) Meeting
April 27-29, 2021

AGENDA (cont.)

On April 28, 2021, the committee will receive updates on the following products: (1) BLA 125514/S-017, trade name KEYTRUDA (pembrolizumab), submitted by Merck Sharp & Dohme Corp., indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy; and (2) BLA 761034/S-001, trade name TECENTRIQ (atezolizumab), submitted by Genentech, Inc., indicated for patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.

TOPIC 1: BLA 125514/S-017

9:00 a.m.	Call to Order	Philip C. Hoffman, MD Chairperson, ODAC
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	Joyce Yu, PharmD Acting Designated Federal Officer, ODAC
9:10 a.m.	FDA Introductory Comments on Accelerated Approval for Oncology Drug Products: Regulatory Overview	Julia Beaver, MD Chief of Medical Oncology, OCE Deputy Director (acting) OOD, OND, CDER, FDA
9:20 a.m.	APPLICANT PRESENTATIONS	Merck Sharp & Dohme Corp.
	KEYTRUDA in Urothelial Carcinoma	Scot Ebbinghaus, MD Vice President, Oncology Clinical Research Merck & Co., Inc.
	Disease Background and Unmet Need	Arjun Balar, MD Associate Professor of Medicine Director Genitourinary Medical Oncology Program Medical Director, Clinical Trials Office Laura and Isaac Perlmutter Cancer Center
	Efficacy and Safety	Blanca Homet, MD, PhD Distinguished Scientist, Oncology Clinical Research Merck & Co., Inc.
	Potential Options and Timing to Confirm the Benefit of Pembrolizumab and Fulfill the PMR	Blanca Homet, MD, PhD

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Oncologic Drugs Advisory Committee (ODAC) Meeting
April 27-29, 2021

AGENDA (cont.)

9:50 a.m. **FDA PRESENTATION**

Pembrolizumab
1st-line Treatment of Cisplatin Ineligible
Patients with Urothelial Cancer

Laleh Amiri-Kordestani, MD
Director
DO1, OOD, OND, CDER, FDA

10:10 a.m. Clarifying Questions to Presenters

10:40 a.m. **BREAK**

10:55 a.m. **OPEN PUBLIC HEARING**

11:15 a.m. Questions to the Committee/Committee
Discussion

11:45 a.m. **LUNCH**

TOPIC 2: BLA 761034/S-001

12:15 p.m. Call to Order

Philip C. Hoffman, MD
Chairperson, ODAC

12:20 p.m. Introduction of Committee and Conflict
of Interest Statement

Joyce Yu, PharmD
Acting Designated Federal Officer, ODAC

12:25 p.m. FDA Introductory Comments on
Accelerated Approval for Oncology Drug
Products: Regulatory Overview

Julia Beaver, MD
Chief of Medical Oncology, OCE
Deputy Director (acting)
OOD, OND, CDER, FDA

12:35 p.m. **APPLICANT PRESENTATIONS**

Genentech, Inc.

Introduction

Charles Fuchs, MD
Senior Vice President, Product Development
Oncology
Genentech, a Member of the Roche Group

Sponsor's Position on Maintaining the
Accelerated Approval for Atezolizumab
(Tecentriq®) in First Line Metastatic
Urothelial Cancer

Corey A. Carter, MD
Group Medical Director, Product Development
Oncology
Genentech

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Oncologic Drugs Advisory Committee (ODAC) Meeting
April 27-29, 2021

AGENDA (cont.)

1:05 p.m. **FDA PRESENTATION**

Atezolizumab
1st-line Treatment of Cisplatin Ineligible
Patients with Urothelial Cancer (UC)

Laleh Amiri-Kordestani, MD
Director
DO1, OOD, OND, CDER, FDA

1:25 p.m. Clarifying Questions to Presenters

1:55 p.m. **BREAK**

2:10 p.m. **OPEN PUBLIC HEARING**

2:30 p.m. Questions to the Committee/Committee
Discussion

3:00 p.m. **ADJOURNMENT**

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
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AGENDA (cont.)

On April 29, 2021, the committee will receive updates on the following products: (1) BLA 125514/S-024, trade name KEYTRUDA (pembrolizumab), submitted by Merck Sharp & Dohme Corp., indicated for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy; (2) BLA 125514/S-042, trade name KEYTRUDA (pembrolizumab), submitted by Merck Sharp & Dohme Corp., indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib; and (3) BLA 125554/S-041, trade name OPDIVO (nivolumab), submitted by Bristol-Myers Squibb Company, indicated as a single agent for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

TOPIC 1: BLA 125514/S-024

9:00 a.m.	Call to Order	Diane Reidy-Lagunes, MD Acting Chairperson, ODAC
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	Takyiah Stevenson, PharmD Acting Designated Federal Officer, ODAC
9:10 a.m.	FDA Introductory Comments on Accelerated Approval for Oncology Drug Products: Regulatory Overview	Julia Beaver, MD Chief of Medical Oncology, OCE Deputy Director (acting) OOD, OND, CDER, FDA
9:20 a.m.	APPLICANT PRESENTATIONS	Merck Sharp & Dohme Corp.
	Introduction	Nageatte Ibrahim, MD Vice President, Oncology Clinical Research Merck & Co., Inc
	Disease Background and Unmet Need in Gastric Cancer	Peter Enzinger, MD Associate Professor of Medicine Harvard Medical School and Dana-Farber Cancer Institute
	Efficacy, Safety and Proposed Confirmatory Studies of Pembrolizumab in Gastric Cancer	Pooja Bhagia, MD Clinical Development Lead – GI Cancers, Oncology Clinical Research Merck & Co., Inc
	Concluding Remarks	Nageatte Ibrahim, MD

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AGENDA (cont.)

9:50 a.m. **FDA PRESENTATION**

Pembrolizumab
Gastric/Gastroesophageal Junction (GEJ)
Adenocarcinoma (PD-L1 CPS \geq 1)

Steven Lemery, MD, MHS
Acting Director
Division of Oncology 3 (DO3)
OOD, OND, CDER, FDA

10:10 a.m. Clarifying Questions to Presenters

10:40 a.m. **BREAK**

10:50 a.m. **OPEN PUBLIC HEARING**

11:10 a.m. Questions to the Committee/Committee
Discussion

11:40 a.m. **LUNCH**

TOPIC 2: BLA 125514/S-042

12:10 p.m. Call to Order

Philip C. Hoffman, MD
Chairperson, ODAC

12:15 p.m. Introduction of Committee and Conflict
of Interest Statement

Takyiah Stevenson, PharmD
Acting Designated Federal Officer, ODAC

12:20 p.m. FDA Introductory Comments on
Accelerated Approval for Oncology Drug
Products: Regulatory Overview

Julia Beaver, MD
Chief of Medical Oncology, OCE
Deputy Director (acting)
OOD, OND, CDER, FDA

12:30 p.m. **APPLICANT PRESENTATIONS**

Merck Sharp & Dohme Corp.

Introduction

Scot Ebbinghaus, MD
Vice President, Oncology Clinical Research
Merck & Co., Inc.

Efficacy and Safety of Pembrolizumab in
2L HCC

Abby Siegel, MD
Associate Vice President, Oncology Clinical
Research
Merck & Co., Inc

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Clinical Perspectives

Richard Finn, MD

Professor of Medicine, Geffen School of Medicine at UCLA in the Department of Medicine, Division of Hematology/Oncology

Conclusions

Scot Ebbinghaus, MD

1:00 p.m.

FDA PRESENTATION

Pembrolizumab Hepatocellular Carcinoma (HCC)

Steven Lemery, MD, MHS

Acting Director
DO3, OOD, OND, CDER, FDA

1:20 p.m.

Clarifying Questions to Presenters

1:50 p.m.

BREAK

2:00 p.m.

OPEN PUBLIC HEARING

2:20 p.m.

Questions to the Committee/Committee Discussion

2:50 p.m.

BREAK

TOPIC 3: BLA 125554/S-041

3:00 p.m.

Call to Order

Philip C. Hoffman, MD

Chairperson, ODAC

3:05 p.m.

Introduction of Committee and Conflict of Interest Statement

Takyiah Stevenson, PharmD

Acting Designated Federal Officer, ODAC

3:10 p.m.

FDA Introductory Comments on Accelerated Approval for Oncology Drug Products: Regulatory Overview

Julia Beaver, MD

Chief of Medical Oncology, OCE
Deputy Director (acting)
OOD, OND, CDER, FDA

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AGENDA (cont.)

3:20 p.m.	APPLICANT PRESENTATIONS	Bristol-Myers Squibb Company
	Nivolumab (Opdivo®) Introduction	Mathias Hukkelhoven, PhD Senior Vice President, Global Regulatory and Safety Sciences Bristol Myers Squibb
	Unmet Need in HCC	Thomas Abrams, MD Assistant Professor of Medicine, Harvard Medical School Dana Farber Cancer Institute
	Efficacy & Safety CheckMate-040 and -459	Ashwin Sama, MD Clinical Development Lead, HCC Bristol Myers Squibb
	Nivolumab HCC Clinical Development Program	Ian Waxman, MD Vice President, GI Development Team Lead Bristol Myers Squibb
	Nivolumab HCC Clinical Perspective	Anthony El-Khoueiry, MD Associate Professor of Clinical Medicine, Keck School of Medicine CISO Chair, USC Norris Comprehensive Cancer Center University of Southern California
3:50 p.m.	FDA PRESENTATION	
	Nivolumab Hepatocellular Carcinoma (HCC)	Steven Lemery, MD, MHS Acting Director DO3, OOD, OND, CDER, FDA
4:10 p.m.	Clarifying Questions to Presenters	
4:40 p.m.	BREAK	
4:50 p.m.	OPEN PUBLIC HEARING	
5:10 p.m.	Questions to the Committee/Committee Discussion	
5:40 p.m.	ADJOURNMENT	