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

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

DRAFT 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 ≥ 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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DRAFT AGENDA (cont.)

1:50 p.m.	**FDA PRESENTATION**	
	Atezolizumab + Nab-Paclitaxel PDL-1 + mTNBC	**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**	

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DRAFT 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**

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

DRAFT AGENDA (cont.)

1:05 p.m.	**FDA PRESENTATION**	
	Atezolizumab 1st-line Treatment of Cisplatin Ineligible Patients with Urothelial Cancer	**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**	

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DRAFT 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**

9:50 a.m.	**FDA PRESENTATION**	
	Pembrolizumab Gastric/Gastroesphageal Junction (GEJ) Adenocarcinoma (PD-L1 CPS ≥ 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

	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 Hepatocelluar 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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DRAFT 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**	