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

Oncologic Drugs Advisory Committee Meeting

March 15, 2024

DRAFT AGENDA

During the morning session, the Committee will discuss supplemental biologics license application (sBLA) 125746.74 for CARVYKTI (ciltacabtagene autoleucel), suspension for intravenous infusion, submitted by Janssen Biotech, Inc. The proposed indication for this product is for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one prior line of therapy, including a proteasome inhibitor, and an immunomodulatory agent, and are refractory to lenalidomide. The Committee will have a general discussion focused on the overall survival data in the Study MMY3002 (CARTITUDE-4) and the risk and benefit of ciltacabtagene autoleucel in the intended population. During the afternoon session, the Committee will discuss sBLA 125736.218 for ABECMA (idecabtagene vicleucel), suspension for intravenous infusion, submitted by Celgene Corp., a Bristol-Myers Squibb Co. The proposed indication is for the treatment of adult patients with relapsed or refractory multiple myeloma who have received an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. The Committee will have a general discussion focused on the overall survival data in the Study MM-003 (KarMMa-3) and the risk and benefit of idecabtagene vicleucel in the intended population.

8:30 a.m.	Call to Order	**Ravi A. Madan, MD** Chairperson, ODAC
8:35 a.m.	Introduction of Committee/ Conflict of Interest Statement	**Joyce Frimpong, PharmD** Acting Designated Federal Officer, ODAC
8:40 a.m.	FDA Opening Remarks	**Robert Sokolic, MD** Branch Chief Malignant Hematology Branch (MHB) Division of Clinical Evaluation Hematology (DCEH) Office of Clinical Evaluation (OCE) Office of Therapeutic Products (OTP) Center for Biologics Evaluation and Research (CBER), FDA
8:45 a.m.	**GUEST SPEAKER PRESENTATION** Current Management of Multiple Myeloma	**Sham Mailankody, MBBS** Clinical Director, Cellular Therapy Service Research Director, Myeloma Service Associate Attending Physician and Associate Member Memorial Sloan Kettering Cancer Center
9:10 a.m.	Clarifying Questions to Guest Speaker	

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

Oncologic Drugs Advisory Committee Meeting

March 15, 2024

DRAFT AGENDA (cont.)

9:20 a.m.	**APPLICANT PRESENTATIONS**	**Janssen Biotech Inc.**
	Introduction	**Sen Zhuang, MD, PhD** Vice President, Oncology Research & Development, Johnson & Johnson
	Unmet Need	**Irene Ghobrial, MD** Professor of Medicine Dana Farber Cancer Institute Harvard Medical School
	CARTITUDE-4 Efficacy and Safety Data	**Jordan Schecter, MD** Vice President Research & Development Johnson & Johnson
	Clinical Perspective	**Sundar Jagannath, MBBS** Director of Center of Excellence for Multiple Myeloma Tisch Cancer Institute Professor of Medicine at Icahn School of Medicine Mount Sinai
10:05 a.m.	**FDA PRESENTATIONS**	
	Ciltacabtagene Autoleucel (CARVYKTI) sBLA 125746.74	**Helkha Peredo-Pinto, MD, MPH** Clinical Reviewer MHB, DCEH, OCE, OTP, CBER, FDA **Cong Wang, PhD** Statistical Reviewer Therapeutics Evaluation Branch 1 (TEB1) Division of Biostatistics (DB) Office of Biostatistics and Pharmacovigilance (OBPV), CBER, FDA
10:35 a.m.	Clarifying Questions	
11:05 a.m.	**BREAK**	

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

Oncologic Drugs Advisory Committee Meeting

March 15, 2024

DRAFT AGENDA (cont.)

11:20 a.m.	**OPEN PUBLIC HEARING**	
11:50 a.m.	Questions to the Committee/Committee Discussion	
12:50 p.m.	**LUNCH**	
1:25 p.m.	Call to Order	**Ravi A. Madan, MD** Chairperson, ODAC
1:30 p.m.	Introduction of Committee/ Conflict of Interest Statement	**Joyce Frimpong, PharmD** Acting Designated Federal Officer, ODAC
1:35 p.m.	FDA Opening Remarks	**Robert Sokolic, MD** Branch Chief MHB, DCEH, OCE, OTP, CBER, FDA
1:45 p.m.	**APPLICANT PRESENTATIONS**	**Celgene Corporation, a Bristol-Myers Squibb Company**
	Introduction	**Anne Kerber, MD** Senior Vice President, Head of Late Clinical Development, Hematology, Oncology, and CT Bristol Myers Squibb
	Disease Background	**Sagar Lonial, MD** Chief Medical Officer, Winship Cancer Institute of Emory University Professor and Chair, Department of Hematology and Medical Oncology Anne and Bernard Gray Family Chair in Cancer Emory University School of Medicine
	KarMMa-3 Design and PFS Results	**Eric Bleickardt, MD** Vice President, Late Clinical Development, Cell Therapy Bristol Myers Squibb
	KarMMa-3 Overall Survival Results	**Eric Bleickardt, MD**

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

Oncologic Drugs Advisory Committee Meeting

March 15, 2024

DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Clinical Safety	**Mark Cook, MBChB, PhD** Senior Clinical Trial Physician Bristol Myers Squibb
	Clinical Perspective on Benefits and Risks of Ide-cel Treatment for Triple-class Exposed Multiple Myeloma Patients	**Noopur Raje, MD** Director, Center for Multiple Myeloma Massachusetts General Hospital Professor of Medicine Harvard Medical School
2:30 p.m.	**FDA PRESENTATIONS**	
	Idecabtagene Vicleucel (ABECMA) sBLA 125736.218	**Poornima Sharma, MD** Clinical Reviewer MHB, DCEH, OCE, OTP, CBER, FDA **Xue (Mary) Lin, PhD** Statistical Reviewer TEB1, DB, OBPV, CBER, FDA
3:15 p.m.	Clarifying Questions	
3:45 p.m.	**BREAK**	
4:00 p.m.	**OPEN PUBLIC HEARING**	
4:30 p.m.	Questions to the Committee/Committee Discussion	
5:30 p.m.	**ADJOURNMENT**	