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

Oncologic Drugs Advisory Committee (ODAC)

May 20-21, 2025

AGENDA

On the morning of May 20, 2025, the Committee will discuss supplemental biologics license application (sBLA) 761309/S-001, for COLUMVI (glofitamab) injection, submitted by Genentech, Inc. The proposed indication (use) is in combination with gemcitabine and oxaliplatin for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) who are not candidates for autologous stem cell transplant (ASCT).

On the afternoon of May 20, 2025, the Committee will discuss sBLA 761145/S-029, for DARZALEX FASPRO (daratumumab and hyaluronidase) injection, for subcutaneous use, submitted by Janssen Biotech, Inc. The proposed indication (use) is as monotherapy for the treatment of adult patients with high-risk smoldering multiple myeloma (SMM).

On the morning of May 21, 2025, the Committee will discuss new drug application (NDA) 215793, for UGN-102 (mitomycin) for intravesical solution, submitted by UroGen Pharma, Inc. The proposed indication (use) is for the treatment of adult patients with low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).

On the afternoon of May 21, 2025, the Committee will discuss supplemental new drug application (sNDA) 211651/S-013, for TALZENNA (talazoparib) capsules, submitted by Pfizer Inc. The proposed indication (use) is in combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC).

May 20, 2025, Morning Session

8:00 a.m.	Call to Order and Introduction of Committee	**Neil Vasan, MD, PhD** Acting Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	**Jessica Seo, PharmD** Acting Designated Federal Officer, ODAC
8:10 a.m.	**FDA OPENING REMARKS**	
	Glofitamab-gxbm	**Nicole Gormley, MD** Director Division of Hematologic Malignancies II (DHM II) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
	Glofitamab-gxbm (COLUMVI) BLA 761309	**Margret Merino, MD** Clinical Team Leader DHM II, OOD, OND, CDER, FDA
8:30 a.m.	**APPLICANT PRESENTATIONS**	**Genentech, Inc.**
	Introduction	**Charles Fuchs, MD, MPH** Genentech, Inc.

AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	DLBCL Background & Unmet Need	**Jeremy Abramson, MD** Massachusetts General Hospital Cancer Center
	STARGLO Efficacy & Safety	**Michelle Boyer, PhD** Genentech, Inc.
	STARGLO Subgroup Analyses	**Venkat Sethuraman, PhD** Genentech, Inc.
	Clinical Perspective	**Krish Patel, MD** Sarah Cannon Research Institute
	Closing Remarks	**Charles Fuchs, MD, MPH**
	FDA WELCOME	**Martin A. Makary, MD, MPH** Commissioner FDA
		Vinayak Kashyap Prasad MD, MPH Director Center for Biologics Evaluation and Research (CBER), FDA
9:15 a.m.	**FDA PRESENTATIONS**	
	Glofitamab-gxbm (COLUMVI) BLA 761309	**Nicole Sunseri, MD, PhD** Clinical Reviewer DHM II, OOD, OND, CDER, FDA
9:55 a.m.	Clarifying Questions	
10:20 a.m.	**BREAK**	
10:30 a.m.	**OPEN PUBLIC HEARING**	
11:00 a.m.	Questions to the Committee/Committee Discussion	
12:00 p.m.	**LUNCH**	

AGENDA (cont.)

May 20, 2025, Afternoon Session

1:00 p.m.	Call to Order and Introduction of Committee	**Neil Vasan, MD, PhD** Acting Chairperson, ODAC
1:05 p.m.	Conflict of Interest Statement	**Jessica Seo, PharmD** Acting Designated Federal Officer, ODAC
1:10 p.m.	**FDA OPENING REMARKS**	
	BLA 761145 Daratumumab and hyaluronidase-fihj (Dara SC) (DARZALEX FASPRO)	**Bindu Kanapuru, MD** Supervisory Associate Director for Therapeutic Review DHM II, OOD, OND, CDER, FDA
1:30 p.m.	**APPLICANT PRESENTATIONS**	**Janssen Research & Development, LLC**
	Introduction	**Sen Zhuang, MD, PhD** Vice President, Oncology Research & Development Johnson & Johnson
	Unmet Need	**Sagar Lonial, MD, FACP** Chair and Professor Department of Hematology and Medical Oncology Anne and Bernard Gray Family Chair in Cancer Chief Medical Officer Winship Cancer Institute Emory University School of Medicine
	Efficacy	**Robin Carson, MD** Vice President, Clinical Leader Oncology Johnson & Johnson
	Safety	**Robyn Dennis, MD** Senior Medical Director, Oncology Johnson & Johnson
	Clinical Perspective	**S. Vincent Rajkumar, MD, FRCPC** Edward W. and Betty Knight Scripps Professor of Medicine Mayo Clinic

AGENDA (cont.)

2:15 p.m.	**FDA PRESENTATIONS**	
	BLA 761145 Daratumumab and hyaluronidase-fihj (DARZALEX FASPRO)	**Payal Aggarwal, DO, MS** Clinical Reviewer DHM II, OOD, OND, CDER, FDA
2:55 p.m.	Clarifying Questions	
3:20 p.m.	**BREAK**	
3:30 p.m.	**OPEN PUBLIC HEARING**	
4:00 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	

May 21, 2025, Morning Session

8:00 a.m.	Call to Order and Introduction of Committee	**Daniel Spratt, MD** Acting Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	**Jessica Seo, PharmD** Acting Designated Federal Officer, ODAC
8:10 a.m.	**FDA OPENING REMARKS**	
	UGN-102 (Mitomycin)	**Sundeep Agrawal, MD** Clinical Team Leader Genitourinary Malignancies Division of Oncology 1 (DO1) OOD, OND, CDER, FDA
8:35 a.m.	**APPLICANT PRESENTATIONS**	**UroGen Pharma, Inc.**
	Introduction	**Mark Schoenberg, MD** Chief Medical Officer UroGen Pharma, Inc.
	Unmet Need	**Sam S. Chang, MD** Chief, Division of Urologic Oncology Chief Surgical Officer Vanderbilt Ingram Cancer Center
	APPLICANT PRESENTATIONS (CONT.)	

AGENDA (cont.)

	Efficacy	**Michael J. Louie, MD, MPH, MSc** EVP, Clinical Development and Medical Affairs UroGen Pharma, Inc.
	Safety	**Sunil Raju, MBBS, BSc** Vice President, Clinical Development UroGen Pharma, Inc.
	Clinical Perspective	**Max Kates, MD** Division Director, Urologic Oncology Brady Urological Institute Johns Hopkins Greenberg Bladder Cancer Institute
	Conclusion	**Mark Schoenberg, MD**
9:20 a.m.	**FDA PRESENTATIONS**	
	NDA 215793: UGN-102 (mitomycin intravesical solution)	**Brian Heiss, MD** Clinical Reviewer Genitourinary Malignancies DO1, OOD, OND, CDER, FDA
9:50 a.m.	Clarifying Questions	
10:20 a.m.	**BREAK**	
10:30 a.m.	**OPEN PUBLIC HEARING**	
11:00 a.m.	Questions to the Committee/Committee Discussion	
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May 21, 2025, Afternoon Session

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1:05 p.m.	Conflict of Interest Statement	**Jessica Seo, PharmD** Acting Designated Federal Officer, ODAC
1:10 p.m.	**FDA OPENING REMARKS**	
	Talazoparib with Enzalutamide for Metastatic Castration-Resistant Prostate Cancer (mCRPC)	**Jaleh Fallah, MD** Clinical Team Leader (Acting) Genitourinary Malignancies DO1, OOD, OND, CDER, FDA
1:30 p.m.	**APPLICANT PRESENTATIONS**	**Pfizer, Inc.**

AGENDA (cont.)

	Introduction	**Johanna Bendell, MD** Chief Development Officer Oncology Research and Development Pfizer, Inc.
	Treatment Landscape	**Pedro Barata, MD, MSc, FACP** Associate Professor of Medicine Case Western Reserve University School of Medicine Case Comprehensive Cancer Center Cleveland, Ohio
	Efficacy and Safety	**Dana Kennedy, PharmD, BCOP** **Vice President** Genitourinary Therapeutic Area Head Oncology Research and Development Pfizer, Inc.
	Clinical Perspective	**Neeraj Agarwal, MD, FASCO** Professor of Medicine & Presidential Endowed Chair of Cancer Research Huntsman Cancer Institute University of Utah
	Closing Remarks	**Johanna Bendell, MD**
2:15 p.m.	**FDA PRESENTATIONS**	
	Talazoparib with Enzalutamide for Metastatic Castration-Resistant Prostate Cancer (mCRPC)	**William Maguire, MD, PhD** Clinical Reviewer Genitourinary Malignancies DO1, OOD, OND, CDER, FDA
2:55 p.m.	Clarifying Questions	
3:20 p.m.	**BREAK**	
3:30 p.m.	**OPEN PUBLIC HEARING**	
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