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

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

AGENDA

The committee will discuss supplemental biologics license application (BLA) 761121/S-008, for POLIVY (polatuzumab vedotin-piiq) for injection, submitted by Genentech, Inc. The proposed indication (use) for this product is in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL). This product was approved under 21 CFR 601.41 (subpart E, accelerated approval regulations) for use in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified, after at least two prior therapies. Confirmatory studies are post-marketing studies to verify and describe the clinical benefit of a product after it receives accelerated approval. The new proposed indication is based on the confirmatory study, POLARIX (Study GO39942), conducted to fulfill post-marketing requirement 3630-1 detailed in the June 10, 2019, approval letter, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/761121Orig1s000ltr.pdf. Based on the results of the POLARIX study, the committee will discuss the benefit-risk profile of POLIVY in patients with previously untreated DLBCL.

12:00 p.m.	Call to Order	**Jorge Garcia, MD, FACP** Chairperson, ODAC
12:05 p.m.	Introduction of Committee and Conflict of Interest Statement	**She-Chia Jankowski, PharmD** Designated Federal Officer, ODAC
12:10 p.m.	FDA Introductory Comments	
	Polatuzumab Vedotin-piiq for First-Line Treatment of Diffuse Large B-Cell Lymphoma	**Yvette Kasamon, MD** Clinical Team Leader Division of Hematologic Malignancies II (DHM II) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
12:30 p.m.	**APPLICANT PRESENTATIONS**	**Genentech, Inc.**
	Introduction	**Charles Fuchs, MD** Genentech, Inc.
	DLBCL Background & Unmet Need	**Christopher Flowers, MD, MS, FASCO** M.D. Anderson Cancer Center, Houston
	POLARIX Efficacy & Safety	**Jamie Hirata, PharmD** Genentech, Inc.

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Clinical Perspective	**Jonathan Friedberg, MD, MMSc** Wilmot Cancer Institute, University of Rochester
	Closing Remarks	**Charles Fuchs, MD** Genentech, Inc.
1:15 p.m.	**FDA PRESENTATIONS**	
	Polatuzumab Vedotin-piiq BLA 761121/Supplement 008	**Maryam Yazdy, MD** Clinical Reviewer, DHM II, OOD, OND, CDER, FDA
2:00 p.m.	Clarifying Questions to Presenters	
3:00 p.m.	**BREAK**	
3:30 p.m.	**OPEN PUBLIC HEARING**	
4:30 p.m.	Questions to the Committee/Committee Discussion	
5:15 p.m.	**ADJOURNMENT**	