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

Oncologic Drugs Advisory Committee (ODAC) Meeting
November 16, 2023

AGENDA

The Committee will receive updates on the accelerated approval program in oncology and two new drug applications (NDAs) approved under 21 CFR 314.500 (subpart H, accelerated approval regulations) that have not met their agreed-upon milestones for completion of confirmatory trial(s). Confirmatory trials are postmarketing studies to verify and describe the clinical benefit of a drug after it receives accelerated approval. These updates will provide information on the status of all accelerated approvals granted in oncology, including products with delayed confirmatory trials, and the status of confirmatory trials for the specific NDAs to be discussed, including any ongoing and planned trials.

The two products to be discussed are: (1) FOLOTYN (pralatrexate), NDA 022468 submitted by Acrotech Biopharma Inc, indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL), and (2) BELEODAQ (belinostat), NDA 206256 submitted by Acrotech Biopharma Inc, indicated for the treatment of patients with relapsed or refractory PTCL. Based on the updates provided, the Committee will have a general discussion about delayed confirmatory trials as well as a focused discussion on next steps for the two products, FOLOTYN (pralatrexate) and BELEODAQ (belinostat), approved for PTCL. The overall goal will be the continued optimization of the accelerated approval process with a focus on decreasing the amount of time to verify (or fail to verify) clinical benefit, while continuing to provide early availability of promising oncology products.

9:00 a.m.	Call to Order and Introduction of Committee	**Andy Chen, MD, PhD** Acting Chairperson, ODAC
9:05 a.m.	Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Acting Designated Federal Officer, ODAC
9:10 a.m.	FDA Opening Remarks	
	Timely Completion of Confirmatory Trials after Oncology Accelerated Approvals	**Gautam Mehta, MD** Acting Cross-Disciplinary Team Leader Division of Oncology Products 2 Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
9:30 a.m.	Clarifying Questions	
9:45 a.m.	FDA Introductory Comments	**Nicholas Richardson, DO, MPH** Deputy Director Division of Hematologic Malignancies 2 (DHM2) OOD, OND, CDER, FDA
10:00 a.m.	**APPLICANT PRESENTATIONS**	**Acrotech Biopharma Inc**
	Introduction	**Ashish Anvekar** President Acrotech Biopharma

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Disease Background and Treatment Landscape	**Owen A. O'Connor, MD, PhD** American Cancer Society Research Professor Professor of Medicine, University of Virginia Comprehensive Cancer Center Director, Translational Orphan Blood Cancer Research Center Director, Program for T-Cell Lymphoma Research Professor, Microbiology, Immunology and Cancer Biology University of Virginia
	Post Marketing Requirements (PMR) Studies: Phase 1 Results and Phase 3 Design	**Swaminathan Iyer, MD** Professor of Medicine Director, T Cell Lymphoma Program Department of Lymphoma / Myeloma University of Texas MD Anderson Cancer Center
	PMR Study Timeline	**Ashish Anvekar**
10:45 a.m.	**FDA PRESENTATIONS**	
	Pralatrexate (NDA 022468) and Belinostat (NDA 206256)	**Yvette Kasamon, MD** Clinical Team Leader DHM2, OOD, OND, CDER, FDA
11:15 a.m.	Clarifying Questions	
11:30 a.m.	**BREAK**	
11:45 a.m.	**OPEN PUBLIC HEARING**	
12:45 p.m.	Questions to the Committee/Committee Discussion	
1:30 p.m.	**ADJOURNMENT**	