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

Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
May 14, 2019

AGENDA

During the morning session, the committee will discuss new drug application (NDA) 211810 for pexidartinib capsule, application submitted by Daiichi Sankyo, Inc. The proposed indication (use) for this product is for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) also referred to as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS), which is associated with severe morbidity or functional limitations, and which is not amenable to improvement with surgery.

8:00 a.m.	Call to Order and Introduction of Committee	**Brian I. Rini, MD, FACP** Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	**Jennifer Shepherd, RPh** Acting Designated Federal Officer, ODAC
8:10 a.m.	Introductory Comments	**Lola Fashoyin-Aje, MD, MPH** Cross-Discipline Team Leader Division of Oncology Products 2 (DOP2) Office of Hematology & Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Daiichi Sankyo, Inc.**
	Introduction	**Eric Richards, MS, MPH** Vice President Global Head Regulatory Affairs, Oncology Daiichi Sankyo, Inc.
	TGCT Disease Background and Treatment Landscape	**Nicholas Bernthal, MD** Chief, Division of Musculoskeletal Oncology Department of Orthopaedic Surgery David Geffen School of Medicine at UCLA
	Development Program and Efficacy	**William D. Tap, MD** Sarcoma Medical Oncology Service Chief Memorial Sloan Kettering Cancer Center

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	General Safety Assessment of Pexidartnib	**Antoine Yver, MD, MSc** Executive Vice President and Global Head Oncology R&D Daiichi Sankyo, Inc.
	Hepatic Safety	**Laurie DeLeve, MD, PhD** Professor of Medicine University of Southern California Keck School of Medicine Division of Gastrointestinal and Liver Diseases
	Risk Evaluation and Mitigation Strategy (REMS)	**Eric Richards, MS, MPH**
	Clinical Perspective	**William D. Tap, MD**
9:00 a.m.	**FDA PRESENTATIONS**	
	Background & Safety Results and Issues	**Christy Osgood, MD** Clinical Reviewer DOP2, OHOP, OND, CDER, FDA
	Efficacy Results and Issues	**Mallorie Fiero, PhD** Statistics Reviewer Division of Biometrics V (DBV) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
9:45 a.m.	Clarifying Questions	
10:15 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**	

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AGENDA (cont.)

During the afternoon sesssion, the committee will discuss new drug application (NDA) 212166 for quizartinib tablets, application submitted by Daiichi Sankyo, Inc. The proposed indication (use) for this product is for the treatment of adults with relapsed or refractory acute myeloid leukemia (AML) which is FLT3-ITD positive, as detected by an FDA-approved test.

1:00 p.m.	Call to Order and Introduction of Committee	**Brian I. Rini, MD, FACP** Chairperson, ODAC
1:05 p.m.	Conflict of Interest Statement	**Jennifer Shepherd, RPh** Acting Designated Federal Officer, ODAC
1:10 p.m.	Introductory Comments	**Donna Przepiorka, MD, PhD** Cross-Discipline Team Leader Division of Hematology Products (DHP) OHOP, OND, CDER, FDA
1:15 p.m.	**APPLICANT PRESENTATIONS**	**Daiichi Sankyo, Inc.**
	Introduction	**Eric Richards, MS, MPH** Vice President Global Head Regulatory Affairs, Oncology Daiichi Sankyo, Inc.
	Disease Background/Unmet Need	**Mark Levis, MD, PhD** Program Co-Leader, Hematologic Malignancies and Bone Marrow Transplant Program Director, Adult Leukemia Service Johns Hopkins Sidney Kimmel Comprehensive Cancer Center
	Clinical Development and Efficacy	**Jorge Cortes, MD** Deputy Chair and Professor of Medicine Department of Leukemia MD Anderson Cancer Center
	Safety	**Youngsook Choi, MD** Executive Director, Clinical Safety Daiichi Sankyo, Inc.
	Clinical Perspective	**Jorge Cortes, MD**

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2:00 p.m.	**FDA PRESENTATIONS**	
	Introduction and Efficacy Review	**Kunthel By, PhD** Statistical Reviewer DBV, OB, OTS, CDER, FDA
	Safety Review and Summary	**Aviva Krauss, MD** Clinical Reviewer DHP, OHOP, OND, CDER, FDA
2:45 p.m.	Clarifying Questions	
3:15 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**	