

**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

DRAFT 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 Remarks	Lola Fashoyin-Aje, MPH, MD Clinical 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 Los Angeles
	Development Program and Efficacy	William D. Tap, MD Sarcoma Medical Oncology Service Chief Memorial Sloan Kettering Cancer Center

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

General Safety

Antoine Yver, MD, MSc

Executive Vice President and Global Head Oncology
R&D
Daiichi Sankyo, Inc.

Hepatic Safety

Eric Richards, MS, MPH

Clinical Perspective/Benefit-Risk

William D. Tap, MD

9:00 a.m.

FDA PRESENTATIONS

Introduction & Safety

Christy Osgood, MD

Clinical Reviewer
DOP2/OHOP/OND/CDER/FDA

Efficacy

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.

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DRAFT AGENDA (cont.)

During the afternoon session, 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	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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DRAFT AGENDA (cont.)

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**