

**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  
February 26, 2019

**AGENDA**

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*The committee will discuss new drug application (NDA) 212306 for selinexor tablets, application submitted by Karyopharm Therapeutics Inc. The proposed indication (use) for this product is in combination with dexamethasone, for the treatment of patients with relapsed refractory multiple myeloma who have received at least three prior therapies and whose disease is refractory to at least one proteasome inhibitor, at least one immunomodulatory agent, and an anti-CD38 monoclonal antibody.*

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12:30 p.m.	Call to Order and Introduction of Committee	<b>Brian I. Rini, MD, FACP</b> Chairperson, ODAC
12:35 p.m.	Conflict of Interest Statement	<b>Lauren D. Tesh, PharmD, BCPS</b> Designated Federal Officer, ODAC
12:40 p.m.	Introductory Comments	<b>Nicole Gormley, MD</b> Clinical Team Leader Division of Hematology Products (DHP) Office of Hematology and Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
12:55 p.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Karyopharm Therapeutics Inc.</b>
	Introduction	<b>Tanya Lewis</b> Senior Vice President, Global Regulatory Affairs Karyopharm Therapeutics
	Unmet Need in Triple-Class-Refractory MM	<b>Paul Richardson, MD</b> Clinical Program Leader and Director of Clinical Research Jerome Lipper Multiple Myeloma Center Dana Farber Cancer Institute Boston, Massachusetts RJ Corman Professor of Medicine Harvard Medical School
	Efficacy	<b>Jatin Shah, MD</b> Senior Vice President, Clinical Development Karyopharm Therapeutics

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**AGENDA (cont.)**

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**APPLICANT PRESENTATIONS (CONT.)**

Safety

**Michael Kauffman, MD, PhD**  
CEO and Chief Medical Officer  
Karyopharm Therapeutics

Clinical Perspective

**Sundar Jagannath, MD**  
Director of the Multiple Myeloma Program and  
Professor of Medicine The Tisch Cancer Institute  
Mount Sinai, New York

Conclusion

**Sharon Shacham, PhD**  
President and Chief Scientific Officer  
Karyopharm Therapeutics

1:40 p.m. **FDA PRESENTATION**

NDA 212306: Selinexor

**Andrea C. Baines, MD, PhD**  
Clinical Reviewer  
DHP, OHOP, OND, CDER, FDA

2:25 p.m. Clarifying Questions

2:55 p.m. **BREAK**

3:10 p.m. **OPEN PUBLIC HEARING**

4:10 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**