

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

**Oncologic Drugs Advisory Committee (ODAC) Meeting**  
April 21, 2022

**DRAFT AGENDA**

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*The committee will discuss the appropriate approach for phosphatidylinositol-3-kinase inhibitors currently under development in patients with hematologic malignancies and whether randomized data should be required to support a demonstration of substantial evidence of effectiveness and that the drug is safe for its intended use in the proposed population.*

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12:00 p.m.	Call to Order	<b>Jorge Garcia, MD</b> Acting Chairperson, ODAC
12:05 p.m.	Introduction of Committee and Conflict of Interest Statement	<b>She-Chia Chen, PharmD</b> Designated Federal Officer, ODAC
12:10 p.m.	FDA Introductory Comments	<b>Nicole Gormley, MD</b> Director Division of Hematologic Malignancies II (DHM II) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
12:25 p.m.	<b>FDA PRESENTATION</b>	
	Phosphatidylinositol 3-kinase (PI3K) Inhibitors in Hematologic Malignancies	<b>Nicholas Richardson, DO, MPH</b> Clinical Team Leader DHM II, OOD, OND, CDER, FDA
1:10 p.m.	Clarifying Questions to Presenters	
1:50 p.m.	<b>BREAK</b>	
2:00 p.m.	<b>OPEN PUBLIC HEARING</b>	
2:30 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	<b>ADJOURNMENT</b>	