

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

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

AGENDA

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.

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