

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

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

DRAFT 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.

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| 12:00 p.m. | Call to Order | Jorge Garcia, MD
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 | |
| 3:00 p.m. | ADJOURNMENT | |