Activity Outline
FDA Grand Rounds: The Saga of Phosphatidylinositol 3-Kinase (PI3K) Inhibitors
May 12, 2022
Virtual

Activity Coordinator:
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Series Description

The FDA Grand Rounds is webcast monthly to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Lecture Description
Several drugs called phosphatidylinositol 3-kinase or PI3K inhibitors have been FDA approved for patients with chronic lymphocytic leukemia (CLL), a cancer of the blood, and certain types of lymphoma, a cancer of the immune system, such as follicular lymphoma (FL) and marginal zone lymphoma (MZL). The PI3K inhibitor drug class is associated with notable side effects that can be serious or fatal, including infection, diarrhea, liver problems, rash, and inflammation of the lungs. There are clinical trials showing concerns with survival in patients with CLL or lymphoma because of the serious side effects of the PI3K inhibitor drug class. Information on the PI3K inhibitor drug class will be discussed and how it impacts future PI3K inhibitors developed for patients with cancer. Broader considerations in clinical trial design and endpoints for cancer drugs will be discussed, using this drug class as an example.

References

- Cahill KE, Smith SM. Follicular lymphoma: a focus on current and emerging therapies. Oncology (Williston Park) 2022;36:97-106.
- Kay NE, Hampel PJ, Van Dyke DL, Parikh SA. CLL update 2022: A continuing evolution in care. Blood Rev 2022. DOI: 10.1016/j.blre.2022.100930

Series Objectives

- Discuss the research conducted at the FDA
- Explain how FDA science impacts public health

Learning Objectives After completion of this activity, the participant will be able to:

- Identify the side effects associated with the PI3K inhibitor drug class, and how these may impact outcomes such as overall survival.
- Describe the differences in information gained from randomized controlled trials and single-arm trials of cancer drugs.
- Evaluate how the information from a class of products for cancer should impact future development of products in the same class.

Target Audience
This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

Agenda

Lecture 1 May 12, 2022

Time	Topic	Speaker
12:00 - 1:00 PM EDT	The Saga of Phosphatidylinositol 3-Kinase (PI3K) Inhibitors	RICHARDSON NICHOLAS YVETTE KASAMON

Continuing Education Accreditation

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In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-22-006-L04-P for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- KASAMON, YVETTE, Medical Officer, FDA - *nothing to disclose*
- NICHOLAS, RICHARDSON, Medical Officer, FDA/CDER/OHOP/DHP - *nothing to disclose*

Planning Committee

- Dinatale, Miriam, Team Leader, Food and Drug Administration - *nothing to disclose*
- Pfundt, Tiffany, PharmD, Senior Advisor, HHS/ASPR - *nothing to disclose*
- Wheelock, Leslie, RN, MS, Director, OSPD, FDA, OC, OCS, OSPD - *nothing to disclose*

CE Consultation and Accreditation Team

- Bueide, Rachel E., MPhil, Training Specialist, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

All of the relevant financial relationships listed for these individuals have been mitigated.

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.