

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
September 22-23, 2022

AGENDA

During the first session of September 22, 2022, the committee will discuss new drug application (NDA) 215643, for poziotinib tablets, submitted by Spectrum Pharmaceuticals, Inc. The proposed indication (use) for this product is for the treatment of patients with previously treated, locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 exon 20 insertion mutations. Select patients with NSCLC for treatment with poziotinib based on the presence of HER2 exon 20 insertion mutations using an FDA-approved test.

During the second session of September 22, 2022, the committee will hear an update on new drug application (NDA) 214383, for PEPAXTO (melphalan flufenamide) for injection, submitted by Oncopeptides A.B. This product was approved under 21 CFR 314.500 (subpart H, accelerated approval regulations) for use in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. The confirmatory trial demonstrated a worse overall survival and failed to verify clinical benefit. Confirmatory studies are postmarketing studies to verify and describe the clinical benefit of a drug after it receives accelerated approval. Based on the updates provided, the committee will have a general discussion focused on next steps for the product.

9:00 a.m.	Call to Order	Jorge Garcia, MD, FACP Chairperson, ODAC
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	She-Chia Chen, PharmD Designated Federal Officer, ODAC
9:10 a.m.	FDA Introductory Comments	Nicole Drezner, MD Clinical Team Leader Division of Oncology 2 (DO2) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
9:25 a.m.	APPLICANT PRESENTATIONS	Spectrum Pharmaceuticals, Inc.
	Poziotinib for NSCLC Harboring HER2 Exon 20 Insertion Mutations – Poziotinib Introduction	Francois Lebel, MD, FRCPC Executive Vice President R&D Chief Medical Officer Spectrum Pharmaceuticals, Inc.
	Unmet Need and Mechanism of Action	John Heymach, MD, PhD Professor of Medicine and Chair Thoracic/Head and Neck Medical Oncology The University of Texas MD Anderson Cancer Center

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Efficacy

Gajanan Bhat, PhD
Senior Vice President, Clinical and Data Science
Spectrum Pharmaceuticals, Inc.

Safety

Francois Lebel, MD, FRCPC

Clinical Perspective

Mark Socinski, MD
Executive Medical Director
AdventHealth Cancer Institute

10:10 a.m. **FDA PRESENTATIONS**

Poziotinib for HER2 exon 20 insertion
mutation-positive non-small cell lung
cancer (NSCLC)

Justin Malinou, MD
Clinical Reviewer
DO2, OOD, OND, CDER, FDA

Jeanne Fourie-Zirkelbach, PhD
Team Lead, Clinical Pharmacology
Division of Cancer Pharmacology 2
Office of Clinical Pharmacology
Office of Translational Sciences, CDER, FDA

10:55 a.m. Clarifying Questions to Presenters

11:25 a.m. **BREAK**

11:40 a.m. **OPEN PUBLIC HEARING**

12:10 p.m. Questions to the Committee/Committee
Discussion

1:10 p.m. **LUNCH**

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AGENDA (cont.)

1:50 p.m.	Call to Order	Jorge Garcia, MD, FACP Chairperson, ODAC
1:55 a.m.	Introduction of Committee and Conflict of Interest Statement	She-Chia Chen, PharmD Designated Federal Officer, ODAC
2:00 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
2:15 p.m.	APPLICANT PRESENTATIONS	Oncopeptides AB
	Introduction	Jakob Lindberg Chief Executive Officer Chief Scientific Officer Oncopeptides AB
	Treatment Patterns and Unmet Need with Triple-Class Refractory Multiple Myeloma	Paul Richardson, MD R.J. Corman Professor of Medicine Harvard Medical School Dana-Farber Cancer Institute
	OCEAN Study Clinical Results	Klaas Bakker, MD, PhD Executive VP and Chief Medical Officer Oncopeptides AB
	Clinical Perspective	Yvonne Efebera, MD, MPH Professor, Medical Director of Blood and Marrow Transplant and Cellular Therapy Ohio Health
3:00 p.m.	FDA PRESENTATIONS	
	Melphalan flufenamide (PEPAXTO) NDA 214383	Alexandria Schwarsin, MD Clinical Reviewer DHM II, OOD, OND, CDER, FDA
3:45 p.m.	Clarifying Questions to Presenters	

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AGENDA (cont.)

- 4:15 p.m. **BREAK**
- 4:30 p.m. **OPEN PUBLIC HEARING**
- 5:00 p.m. Questions to the Committee/Committee
Discussion
- 6:00 p.m. **ADJOURNMENT**

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AGENDA (cont.)

On September 23, 2022, the committee will hear an update on new drug application (NDA) 211155, for COPIKTRA (duvelisib) capsule, submitted by Secura Bio, Inc. This product was approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for use in the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after at least two prior therapies. The update includes the final overall survival data from the DUO trial (IPI-145-07) submitted in response to post-marketing requirement 3494-3 detailed in the September 24, 2018 approval letter, available at https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/211155Orig2s000ltr.pdf. Based on the updated overall survival information along with the safety data with duvelisib, the committee will discuss a current assessment of benefit-risk.

9:00 a.m.	Call to Order	Jorge Garcia, MD, FACP Chairperson, ODAC
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	She-Chia Chen, PharmD Designated Federal Officer, ODAC
9:10 a.m.	FDA Introductory Comments	Nicholas Richardson, DO, MPH Clinical Team Leader Division of Hematologic Malignancies II (DHM II) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
9:25 a.m.	APPLICANT PRESENTATIONS	Secura Bio, Inc.
	Introduction	David Sidransky, MD Clinical Advisor, Secura Bio Professor of Oncology, John Hopkins University
	Disease Background & Unmet Need in CLL/SLL	Susan O'Brien, MD Professor of Medicine Division of Hematology/Oncology University of California at Irvine
	Efficacy & Safety	Matthew Davids, MD, MMSc Director, Clinical Research Division of Lymphoma Dana Farber Cancer Institute

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Overall Survival and Benefit/Risk **David Sidransky, MD**

Clinical Perspective **Matthew Davids, MD, MMsc**

10:10 a.m. **FDA PRESENTATION**

Duvelisib – NDA 211155 **Deepti Telaraja, MD**
Clinical Reviewer
DHM II, OOD, OND, CDER, FDA

10:55 a.m. Clarifying Questions to Presenters

11:25 a.m. **BREAK**

11:45 a.m. **OPEN PUBLIC HEARING**

12:15 p.m. Questions to the Committee/Committee
Discussion

1:15 p.m. **ADJOURNMENT**