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

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

DRAFT 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

	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**	

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

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

DRAFT 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	

DRAFT 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**

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

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

DRAFT 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/appletter/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** Clincial 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

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

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

DRAFT 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**	