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

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

QUESTIONS

September 22, 2022 AM session

NDA 215643

Poziotinib

Applicant: Spectrum Pharmaceuticals, Inc.

PROPOSED INDICATION:

- 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.

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1. **DISCUSSION:** Discuss the overall risk:benefit of poziotinib 16 mg once daily given its limited response rate with poor durability, high rate of toxicity, inadequate dosage optimization, and delayed confirmatory trial.

2. **VOTE:** Do the current benefits of poziotinib outweigh its risks for the treatment of patients with NSCLC with HER2 exon 20 insertion mutations?

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QUESTIONS (cont.)

September 22, 2022 PM session

NDA 214383

PEPAXTO (melphalan flufenamide)

Applicant: Oncopeptides A.B.

INDICATION:

- 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.

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1. **DISCUSSION:** Discuss the benefit-risk profile of melphalan flufenamide for the currently indicated patient population considering the results of the confirmatory OCEAN trial.

2. **VOTE:** Given the potential detriment in overall survival, failure to demonstrate a progression-free survival benefit, and lack of an appropriate dose, is the benefit-risk profile of melphalan flufenamide favorable for the currently indicated patient population?

QUESTIONS (cont.)

September 23, 2022

NDA 211155

COPIKTRA (duvelisib)

Applicant: Secura Bio, Inc.

INDICATION:

- the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies.

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1. **DISCUSION**: Discuss the benefit-risk profile of duvelisib for the currently indicated population considering the updated results of the DUO trial.

2. **VOTE:** Given the potential detriment in overall survival, duvelisib-associated toxicity, concerns with the selected dose, and the safety issues with the PI3K inhibitor class, is the benefit-risk profile of duvelisib favorable in patients with relapsed or refractory CLL or SLL after at least two prior therapies?