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

Oncologic Drugs Advisory Committee (ODAC) Meeting
March 15, 2024

QUESTIONS

Morning session

sBLA 125746.74

CARVYKTI (ciltacabtagene autoleucel)

Applicant: Janssen Biotech, Inc.

PROPOSED INDICATION:

- the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one prior line of therapy, including a proteasome inhibitor, and an immunomodulatory agent, and are refractory to lenalidomide. The Committee will have a general discussion focused on the overall survival data in the Study MMY3002 (CARTITUDE-4) and the risk and benefit of ciltacabtagene autoleucel in the intended population.

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1. **DISCUSSION:** Discuss whether the results of CARTITUDE-4 are sufficient to support a positive risk-benefit assessment of ciltacabtagene autoleucel for the proposed indication.

2. **DISCUSSION:** Is the risk of early death associated with ciltacabtagene autoleucel treatment acceptable in the context of the PFS benefit?

3. **VOTE:** Is the risk-benefit assessment for ciltacabtagene autoleucel for the proposed indication, favorable?

PFS - progression-free survival

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DRAFT QUESTIONS (cont.)

Afternoon session

sBLA 125736.218

ABECMA (idecabtagene vicleucel)

Applicant: Celgene Corporation, a Bristol-Myers Squibb Company

PROPOSED INDICATION:

- the treatment of adult patients with relapsed or refractory multiple myeloma who have received an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. The Committee will have a general discussion focused on the overall survival data in the Study MM-003 (KarMMa-3) and the risk and benefit of idecabtagene vicleucel in the intended population.

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1. **DISCUSSION:** Discuss whether the results of KarMMa-3 are sufficient to support a positive risk-benefit assessment of idecabtagene vicleucel for the proposed indication.

2. **DISCUSSION:** Is the risk of early death associated with idecabtagene vicleucel treatment acceptable in the context of the PFS benefit?

3. **VOTE:** Is the risk-benefit assessment for idecabtagene vicleucel for the proposed indication, favorable?