

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

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

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

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