

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

***Oncologic Drugs Advisory Committee (ODAC) Meeting***  
August 13, 2020 (AM Session)

**QUESTIONS**

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**BLA 125706**

**Remestemcel-L**

**Applicant: Mesoblast, Inc.**

**PROPOSED INDICATION:** Treatment of steroid-refractory acute graft-versus-host disease (SR-aGVHD) in pediatric patients.

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**Product Characterization Discussion**

1. **DISCUSSION:** Product quality attributes measured for remestemcel-L are intended to ensure that key qualities of the drug product are maintained consistently from lot to lot.

Please discuss the adequacy of the potency assay established by the Applicant for remestemcel-L.

2. **DISCUSSION:** In addition to discussion of potency, please propose and discuss other possible product quality attributes or characteristics that could be controlled to better assure consistent quality of remestemcel-L with regard to safety or effectiveness of the product.