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

***Oncologic Drugs Advisory Committee (ODAC) Meeting***
July 14, 2020

**DRAFT QUESTIONS**

# BLA 761158

# belantamab mafodotin

# Applicant: GlaxoSmithKline Intellectual Property Development Ltd. England

**PROPOSED INDICATION:** For the treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent

1. **DISCUSSION:** Discuss whether the risk of ocular toxicity has been adequately characterized in Study 205678 (DREAMM-2) to allow for an assessment of the benefit-risk profile.

2. **DISCUSSION:** Discuss the impact of ocular toxicity on the benefit-risk profile for belantamab mafodotin.

3. **VOTE:** Does the demonstrated benefit of belantamab mafodotin outweigh the risks in the proposed patient population with multiple myeloma?