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

Oncologic Drugs Advisory Committee (ODAC) Meeting
February 9, 2023

DRAFT QUESTIONS

IND 157775

dostarlimab-gxly

GlaxoSmithKline, LLC

PROPOSED INDICATION: Dostarlimab as a single agent for the treatment of patients with treatment-naïve deficient mismatch repair (dMMR)/microsatellite instability-high (MSI-H) locally advanced rectal cancer (LARC).

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1. **DISCUSSION:** Discuss the adequacy of proposed single-arm trials to evaluate the efficacy and safety of dostarlimab, including the long-term benefits and risks of treatment.

2. **DISCUSSION:** Discuss the adequacy of the proposed clinical endpoints (i.e., complete clinical response rate, event free survival), to characterize and verify the benefit of dostarlimab, including the proposed timing of analyses.

3. **DICUSSION:** Discuss the study population with Stage II/III LARC dMMR/MSI-H for a non-operative management approach.

4. **DISCUSSION:** Discuss the potential impact of the variability in care, expertise, etc., across multi-disciplinary study staff and across study sites on study conduct and ultimately on outcomes.

5. **VOTE:** Will the data from the proposed single arm trials enrolling a total of 130 patients be sufficient to characterize the benefits and risks of dostarlimab in the curative intent setting for patients with dMMR/MSI-H LARC?