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

Oncologic Drugs Advisory Committee (ODAC) Meeting
February 9, 2021

DRAFT QUESTIONS

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sBLA 125514/s-089

KEYTRUDA (pembrolizumab)

Applicant: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

PROPOSED INDICATION: Treatment of patients with high-risk, early-stage triple-negative breast cancer (TNBC), in combination with chemotherapy as neoadjuvant treatment, then as a single agent as adjuvant treatment after surgery.

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1. **VOTE:** Should a regulatory decision on pembrolizumab in combination with multi-agent chemotherapy for neoadjuvant treatment followed by pembrolizumab monotherapy for adjuvant treatment of high-risk early-stage TNBC be deferred until further data are available from future analyses of KEYNOTE-522?