

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
June 24, 2021

DRAFT QUESTIONS

BLA 761209

retifanlimab

Applicant: Incyte Corporation

PROPOSED INDICATION: Treatment of adult patients with locally advanced or metastatic squamous carcinoma of the anal canal (SCAC) who have progressed on or who are intolerant of platinum-based chemotherapy.

1. **DISCUSSION:** Discuss whether the demonstrated magnitude of effect on overall response rate (and duration of response) is clinically meaningful and reasonably likely to predict clinical benefit in patients with recurrent advanced or metastatic squamous cell carcinoma of the anal canal.
2. **VOTE:** Should a regulatory decision on retifanlimab for the treatment of advanced or metastatic SCAC be deferred until further data are available from clinical trial POD1UM-303?