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

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

DRAFT QUESTIONS

BLA 761121/S-008

POLIVY (polatuzumab vedotin-piiq)

Applicant: Genentech, Inc.

PROPOSED INDICATION:

- in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL).

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1. **DISCUSSION:** Discuss the benefit-risk profile of polatuzumab vedotin-piiq in combination with R-CHP for the proposed patient population with large B-cell lymphoma (LBCL), including patients with DLBCL not otherwise specified (NOS), considering the results of the POLARIX trial.

2. **DISCUSSION:** Based on the results of the POLARIX trial, specifically the overall survival results, discuss whether additional follow-up data from POLARIX should be required to inform the benefit-risk of polatuzumab vedotin-piiq in patients with LBCL in the frontline setting.

3. **VOTE:** Given the results of the POLARIX trial, does polatuzumab vedotin-piiq have a favorable benefit-risk in patients with previously untreated LBCL, including DLBCL NOS?