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***APPLICATION NUMBER:***

# 761121Orig1s008

# PRODUCT QUALITY REVIEW(S)

# Memorandum of Assessment:

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| **Submission Tracking Number (STN):** | 761121 Supplement 8, PAS, Efficacy Supplement<br>View submission in docuBridge<br>eCTD Sequence Number 0298 (SDN 300) |
| **Subject:** | Efficacy supplement to support a new indication for treatment of adult patients with previously untreated diffuse large B-cell lymphoma. |
| **Date Received:** | 6/2/2022 |
| **Assessment/Revision Date:** | 7/29/2022 |
| **Primary Assessor:** | Jacek Cieslak, Ph.D., DBRR IV/OBP |
| **Secondary Assessor:** | Leslie Rivera Rosado, Ph.D., Team Leader, DBRR IV/OBP |
| **RPM:** | Wanda Nguyen (clinical); Anita Brown (OPQ/OPRO) |
| **Applicant:** | Genentech, Inc. |
| **Product:** | POLIVY (polatuzumab vedotin-piiq) |
| **Approved indication:** | POLIVY in combination with bendamustine and a rituximab product is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, after at least two prior therapies. |
| **Filing Action Date:** | 8/1/2022 |
| **Action Due Date:** | 4/2/2023 |

## Initial overview of the BLA Supplement for filing:

Genentech submitted this prior approval supplemental BLA (PAS, efficacy supplement) to extend the licensed indication for POLIVY (polatuzumab vedotin-piiq) based on the efficacy and safety data from pivotal Study GO39942/POLARIX entitled, "A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial, Comparing the Efficacy and Safety of Polatuzumab Vedotin in Combination with Rituximab (Rituxan)- Cyclophosphamide, Doxorubicin, and Prednisone (R-CHP) Versus Rituximab- Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in Previously Untreated Patients with Diffuse Large B-Cell Lymphoma (DLBCL)."

The proposed indication is as follows:
POLIVY in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone is indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma.

*The supplement does not provide new product quality information.* ***The supplement is fileable from a product quality perspective.***

## Summary of assessment

This PAS was submitted to extend the licensed indication for POLIVY (polatuzumab vedotin-piiq) as stated above. The supplement does not include any changes related to the product quality information in the BLA. Since the same immunogenicity assays were used to assess the immunogenicity in all arms of the clinical study GO39942, re-assessment of the immunogenicity assays is not needed.

**Environmental Assessment or Claim of Categorical Exclusion**

The applicant claims a categorical exclusion from the requirement to prepare an environmental assessment in accordance with both 21 CFR 25.31(b), which applies to the small molecule linked to the biological, and 21 CFR 25.31(c). The applicant states that this supplemental biologic license application will increase the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion. No extraordinary circumstances exist that would significantly affect the quality of the human environment as a result of the proposed action. *The claim of categorical exclusion is acceptable.*

**Recommendation**

*From a product quality perspective, I recommend approval of this supplement.*

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/s/

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JACEK CIESLAK
07/29/2022 01:32:31 PM

LESLIE A RIVERA ROSADO
07/29/2022 02:03:02 PM