

FACT SHEET

Media Inquiries: (650) 467-6800

About Polivy Combination

Polivy[®] (polatuzumab vedotin-piiq) in combination with a rituximab product, cyclophosphamide, doxorubicin and prednisone (R-CHP) was approved by the U.S. Food and Drug Administration (FDA) as a first treatment for adults who have moderate to high risk diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL).

POLIVY PLUS R-CHP IS THE FIRST FDA-APPROVED THERAPY SINCE 2006 FOR THE FIRST-LINE TREATMENT OF CERTAIN TYPES OF DLBCL

How Polivy is Designed to Work

Polivy is a first-in-class anti-CD79b antibody-drug conjugate (ADC) that binds specifically to CD79b, a protein that is expressed on B cells, including cancer cells.

The therapy is made up of three components: a monoclonal antibody designed to target the CD79b protein, a chemotherapy that destroys dividing cancer cells, and a linker that attaches the chemotherapy to the monoclonal antibody.



What is the Most Important Information I Should Know About Polivy?

The serious to fatal side effects of POLIVY treatment include nerve problems in your arms and legs, infusion-related reactions, low blood cell counts, infections, rare and serious brain infections, tumor lysis syndrome, liver problems, and potential harm to your unborn baby.



When Polivy binds to the CD79b protein on B cells, the entire complex is taken into the cell. Chemotherapy attached to Polivy is then released from the antibody and triggers the destruction of dividing cells, which include cancer cells.

About Diffuse Large B-Cell Lymphoma (DLBCL)

DLBCL is an aggressive, hard-to-treat disease and is the most common form of non-Hodgkin's lymphoma in the United States.¹ Limited progress has been made in improving patient outcomes in previously untreated DLBCL over the last two decades. Although DLBCL often responds to initial treatment, as many as four in 10 people do not respond to or relapse after initial treatment.² Most relapses occur within two years of starting treatment, and the majority of those who require subsequent lines of therapy have poor outcomes.³ DLBCL not otherwise specified (NOS) is the most common category of DLBCL and accounts for about 80% or more of cases.⁴ It applies to cases that do not fall into any specific disease subgroups of DLBCL.



1 OUT OF **3** NHL CASES ARE DLBCL.¹

31,000 PEOPLE IN THE

U.S. ARE PROJECTED TO BE DIAGNOSED WITH DLBCL IN 2023.⁵

66

IS THE MEDIAN AGE AT DIAGNOSIS OF DLBCL.⁶ MEN

Genentech

A Member of the Roche Group 2

ARE SLIGHTLY MORE LIKELY TO DEVELOP DLBCL THAN WOMEN.⁶

Please see additional Important Safety Information in the Polivy full Prescribing Information or visit www.Polivy.com.

www.gene.com M-US-00019495(v1.0)

Common symptoms include:



The most common early sign of DLBCL is painless swelling in one or more lymph nodes. However, the disease may begin somewhere other than the lymph nodes, such as the bones or lungs or even skin, making DLBCL challenging to detect and diagnose.

About Non-Hodgkin's Lymphoma (NHL)

NHL is a disease in which malignant (cancerous) cells form in the lymph system, which is part of the immune system.⁷ NHL occurs when too many abnormal lymphocytes, a type of white blood cell, are produced.⁸ Normally, old lymphocytes die, and the body creates new ones to replace them. In people with NHL, these lymphocytes do not die but continue to grow and divide. This oversupply of lymphocytes crowds into lymph nodes, causing them to swell.⁷





Polivy Plus R-CHP Efficacy and Safety⁹

The U.S. FDA approval of Polivy plus R-CHP for the first-line treatment of certain types of DLBCL is based on pivotal data from the Phase III POLARIX study (879 patients), which showed the risk of disease progression, relapse or death was reduced by 27% in patients treated with Polivy in combination with R-CHP compared to those treated with the standard of care – a rituximab product, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP).

Among the 435 patients treated with Polivy, the most common side effects were nerve problems in arms and legs, nausea, tiredness or lack of energy, diarrhea, constipation, hair loss, and redness and sores of the lining of the mouth, lips, throat, and digestive tract. POLIVY may lower your red or white blood cell counts and increase uric acid levels.

Polivy Plus R-CHP Dosing⁹

DAY 1 Start cycle 1 (treatment) DAYS 2-21 Rest and recovery (no treatment)

Continue receiving the Polivy combination treatment for a total of 6 cycles



Polivy U.S. Indication

POLIVY is a prescription medicine used with other medicines (a rituximab product, cyclophosphamide, doxorubicin, and prednisone) as a first treatment for adults who have moderate to high risk diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL).

Important Safety Information

Possible serious side effects

Everyone reacts differently to POLIVY therapy, so it's important to know what the side effects are. **Some people who have been treated with POLIVY have experienced serious to fatal side effects.** Your doctor may stop or adjust your treatment if any serious side effects occur. **Be sure to contact your healthcare team if there are any signs of these side effects.**

- Nerve problems in arms and legs: This may happen as early as after your first dose and may worsen with every dose. Your doctor will monitor for signs and symptoms, such as changes in your sense of touch, numbness or tingling in your hands or feet, nerve pain, burning sensation, any muscle weakness, or changes to your walking pattern
- Infusion-related reactions: You may experience fever, chills, rash, breathing problems, low blood pressure, or hives within 24 hours of your infusion
- Infections: If you have a fever of 100.4°F (38°C) or higher, chills, cough, or pain during urination, contact your healthcare team.
 Your doctor may also give you medication before giving you POLIVY, which may prevent some infections
- Rare and serious brain infections: Your doctor will monitor closely for signs and symptoms of these types of infections. Contact your doctor if you experience confusion, dizziness or loss of balance, trouble talking or walking, or vision changes



- Tumor lysis syndrome: Caused by the fast breakdown of cancer cells. Signs include nausea, vomiting, diarrhea, and lack of energy
- **Potential harm to liver:** Some signs include tiredness, weight loss, pain in the abdomen, dark urine, and yellowing of your skin or the white part of your eyes. You may be at higher risk if you already had liver problems or you are taking other medication

Side effects seen most often

The most common side effects during treatment were

- Nerve problems in arms and legs
- Nausea
- Tiredness or lack of energy
- Diarrhea
- Constipation
- Hair loss
- · Redness and sores of the lining of the mouth, lips, throat, and digestive tract

POLIVY may lower your red or white blood cell counts and increase uric acid levels.

POLIVY may not be for everyone. Talk to your doctor if you are

- Pregnant or think you are pregnant: Data have shown that POLIVY may harm your unborn baby
- Planning to become pregnant: Women should avoid getting pregnant while taking POLIVY. Women should use effective contraception during treatment and for 3 months after their last POLIVY treatment. Men taking POLIVY should use effective contraception during treatment and for 5 months after their last POLIVY treatment

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

Please see the full Prescribing Information and visit www.Polivy.com for additional Important Safety Information.



^{1.} American Cancer Society. Types of B-cell Lymphoma. https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/b-cell-lymphoma.html.Accessed Mar 7, 2023.

^{2.} Sawalha Y. Relapsed/Refractory Diffuse Large B-Cell Lymphoma: A Look at the Approved and Emerging Therapies. Journal of Personalized Medicine. 2021;11(12):1345. https://doi.org/10.3390/jpm11121345.

^{3.} Wang Y, Farooq U, Link BK, Larson MC, King RL, Maurer MJ, Allmer C, Hefazi M, Thompson CA, Micallef IN, Johnston PB, Habermann TM, Witzig TE, Ansell SM, Cerhan JR, Nowakowski GS. Late Relapses in Patients With Diffuse Large B-Cell Lymphoma Treated With Immunochemotherapy. J Clin Oncol. 2019 Jul 20;37(21):1819-1827. https://doi.org/10.1200/JCO.19.00014.

^{4.} Sehn LH, Salles G. Diffuse Large B-Cell Lymphoma. N Engl J Med. 2021;384(9):842-858. https://www.nejm.org/doi/10.1056/NEJMra2027612. Accessed Apr 11, 2023.

^{5.} Kanas G, Ge W, Quek RGW, Keeven K, Nersesyan K, Jon E Arnason. Epidemiology of diffuse large B-cell lymphoma (DLBCL) and fvollicular lymphoma (FL) in the United States and Western Europe: population-level projections for 2020-2025. *Leuk Lymphoma*. 2022 Jan;63(1):54-63. https://doi.org/10.1080/10428194.2021.1975188. Epub 2021 Sep 11. PMID: 34510995. Accessed Mar 22, 2023.

^{6.} National Cancer Institute. Surveillance, Epidemiology, and End Results Program (SEER). Cancer Stat Facts – NHL. Diffuse Large B-Cell Lymphoma (DLBCL). https://seer.cancer.gov/statfacts/html/ dlbcl.html. Accessed Mar 7, 2023.

^{7.} American Society of Clinical Oncology. Cancer.Net. Lymphoma – Non-Hodgkin: Introduction. https://www.cancer.net/cancer.types/lymphoma-non-hodgkin/introduction. Accessed Mar 7, 2023.

^{8.} American Cancer Society. About Non-Hodgkin Lymphoma. What Is Non-Hodgkin Lymphoma? https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/what-is-non-hodgkin-lymphoma.html. Accessed Mar 7, 2023.

^{9.} Polivy (polatuzumab vedotin-piiq) Prescribing Information. Genentech, Inc. 2023.