SEE 5-YEAR ANALYSIS DATA
LEARN MORE ON PAGE 10

POLIVY® + R-CHP: SUPERIOR Progression-Free Survival (PFS) vs R-CHOP

in the ITT population (HR [95% CI]: 0.73 [0.57, 0.95], p=0.0177)[1]

Indication

POLIVY in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater.

Select Important Safety Information

Serious and sometimes fatal adverse reactions can occur with POLIVY treatment. Peripheral neuropathy, infusion-related reactions, myelosuppression, serious and opportunistic infections, progressive multifocal leukoencephalopathy (PML), tumor lysis syndrome, hepatotoxicity, and embryo-fetal toxicity can occur with POLIVY treatment.

NCCN CATEGORY 1 TREATMENT OPTION

National Comprehensive Cancer Network® (NCCN®) **recommends polatuzumab vedotin-piiq (POLIVY) + R-CHP** (rituximab, cyclophosphamide, doxorubicin, prednisone) as a **category 1** treatment option across **all stages of diffuse large B-cell lymphoma** for certain* patients.[2]

*Category 1 treatment option for patients with previously untreated stage I-II (without extensive mesenteric disease) diffuse large B-cell lymphoma and smIPI score >1; Category 1 preferred treatment option for patients with previously untreated stage II (with extensive mesenteric disease) or stage III-IV diffuse large B-cell lymphoma and IPI score ≥2.

1L = first-line; CI = confidence interval; DLBCL = diffuse large B-cell lymphoma; HGBL = high-grade B-cell lymphoma; HR = hazard ratio; IPI = International Prognostic Index; ITT = intention-to-treat; NCCN = National Comprehensive Cancer Network® (NCCN®); NOS = not otherwise specified; R-CHOP = rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone; smIPI = stage-modified International Prognostic Index.

Please see the full Prescribing Information for additional Important Safety Information.

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Significant unmet need persists in 1L DLBCL[3,4]

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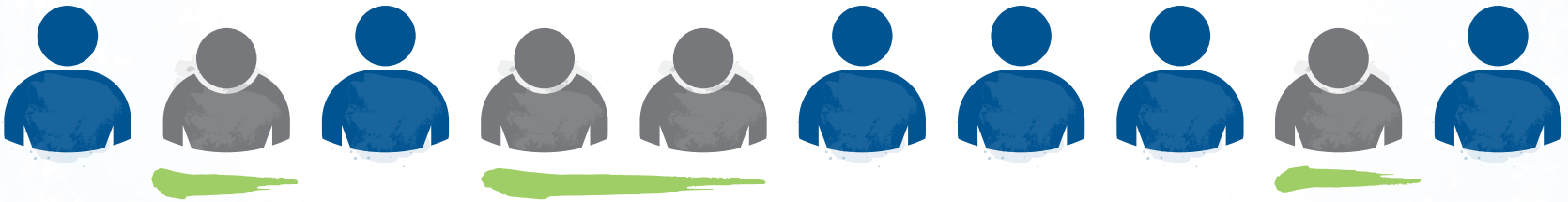
~4 out of 10 patients with DLBCL are at risk of progression after 1L treatment with R-CHOP[5,6]



- The majority of relapses after 1L treatment occur within the first 2 years[7]
- The prognosis of patients with DLBCL diminishes with each subsequent line of therapy[3]
- Subsequent treatments are generally associated with additional toxicity and cost[5,8,9]

New treatments are needed to improve outcomes in patients with 1L DLBCL[4]

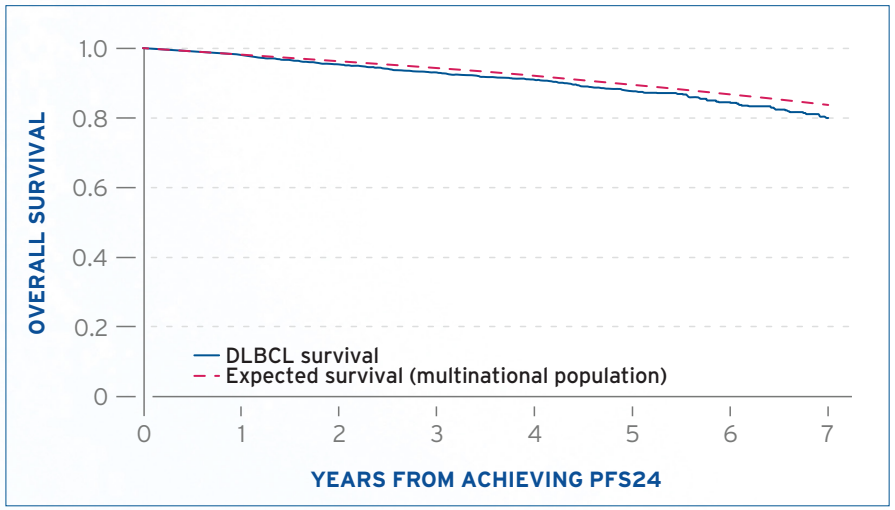
- Over 30,000 new cases of DLBCL are diagnosed per year in the US and this number is expected to increase on a yearly basis[10]
- Patients classified as IPI ≥ 2 are ~2-4 times more likely to relapse within 2 years compared with patients classified as IPI 0-1[11]

Because the risk of progression is so great for patients with DLBCL, the 1L treatment decision is particularly vital[4,12]

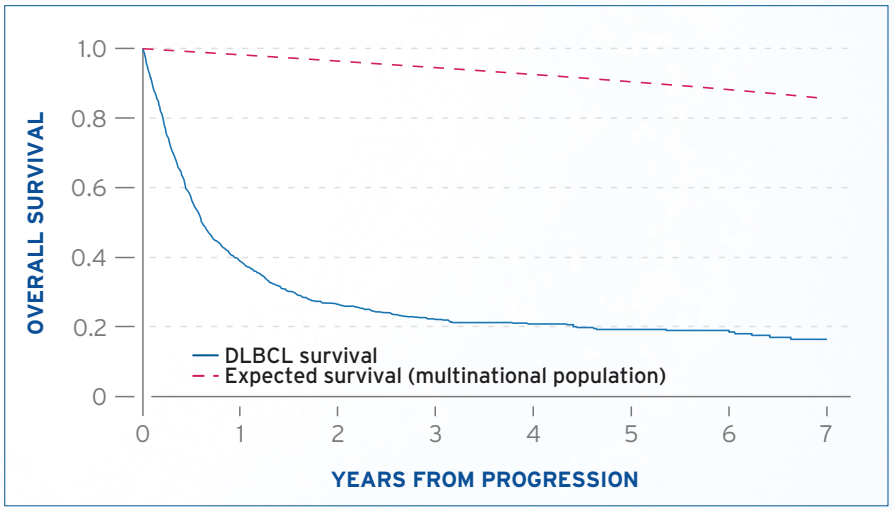
Please see the full Prescribing Information for additional Important Safety Information.

Progression-free survival at 24 months (PFS24) can be a meaningful milestone in frontline DLBCL[7]

Survival Outcomes in Patients Who Were **Progression-Free** at 24 Months



Survival Outcomes in Patients Who **Progressed** Within 24 Months



- Descriptive analysis using individual patient data from patients with newly diagnosed DLBCL in the SEAL database as of July 2016. Patients treated with rituximab-containing, anthracycline-based chemoimmunotherapy as part of initial induction therapy were included in the analysis. The majority of patients were older than 60 years of age (56%), had an ECOG PS of 0-1 (87%), Ann Arbor stage of III-IV (63%), and IPI of 2-5 (64%). OS was calculated for 1423 patients who failed to achieve PFS24 and 3678 patients who were progression-free at 24 months after initiating 1L treatment. OS was compared with the age-, sex-, and country-matched general population via SMR and expected survival using a conditional approach
- **Limitations of this analysis include:** lack of long-term follow-up (>10 years), patients may not reflect the general DLBCL population, analysis being carried out using the PFS definition from the individual clinical trials, underrepresentation of patients >85 years of age, and impact of management was not assessed after relapse
- In POLARIX, PFS24 was not statistically tested and no inferences may be drawn[1]
- Prespecified final analysis of OS in POLARIX showed no statistical difference.[1] See page 13 for more information
- These data should not be interpreted to suggest that POLIVY® confers a survival benefit in this population[1]

ECOG PS = Eastern Cooperative Oncology Group performance status; OS = overall survival; SEAL = Surrogate Endpoints for Aggressive Lymphoma Collaboration; SMR = standardized mortality ratio.

Please see the full Prescribing Information for additional Important Safety Information.

Since the adoption of R-CHOP in 2006, there has been limited therapeutic progress in 1L DLBCL[13]

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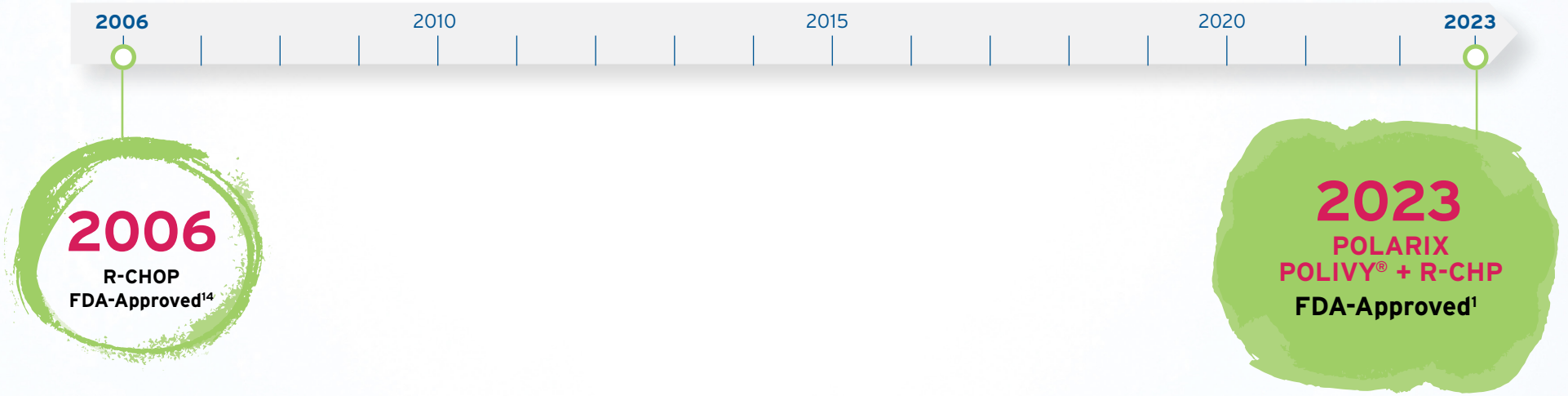
~20 clinical trials evaluating other regimens have been conducted, none of which led to FDA approval[13]



POLIVY + R-CHP represents an important milestone in the treatment of patients with certain types of 1L DLBCL[1]

FDA = US Food and Drug Administration.

Important Safety Information

Peripheral Neuropathy

POLIVY can cause severe peripheral neuropathy. Peripheral neuropathy occurs as early as the first cycle of treatment and is cumulative. POLIVY may exacerbate preexisting peripheral neuropathy.

In POLARIX, of 435 patients treated with POLIVY plus R-CHP, 53% reported new or worsening peripheral neuropathy, with a median time to onset of 2.3 months. Peripheral neuropathy was Grade 1 in 39% of patients, Grade 2 in 12%, and Grade 3 in 1.6%. Peripheral neuropathy resulted in dose reduction in 4% of treated patients and treatment discontinuation in 0.7%. Among patients with peripheral neuropathy after POLIVY, 58% reported resolution after a median of 4 months.

Please see the full Prescribing Information for additional Important Safety Information.

A first-in-class CD79b-directed ADC for the treatment of 1L DLBCL[1]

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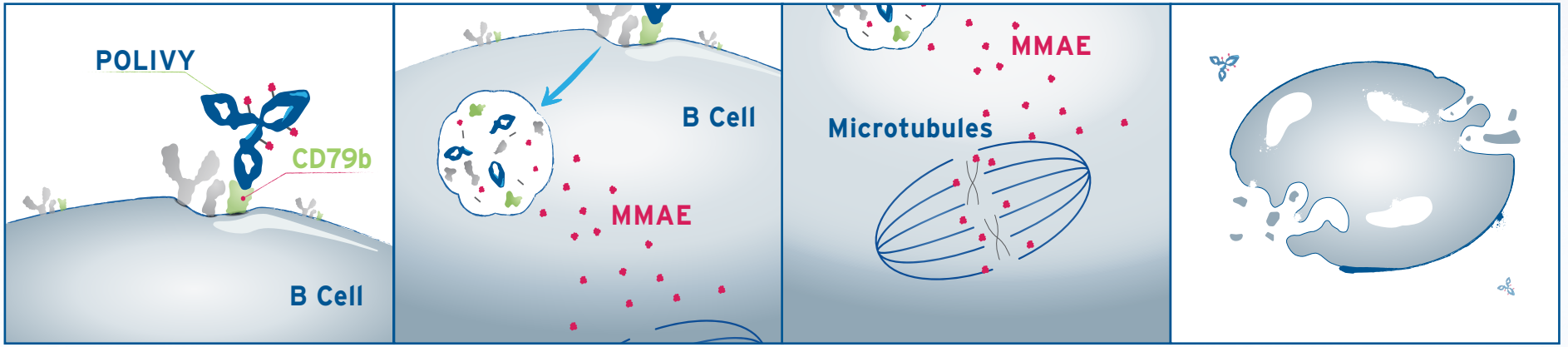
POLIVY® is engineered for targeted activity against dividing B cells



ADC internalization: POLIVY binds to the CD79b portion of the B-cell receptor complex on B cells, triggering internalization of POLIVY and the receptor complex

Cytotoxin delivery: Once internalized, the stable linker is cleaved, releasing MMAE within the B cell

Microtubule disruption and apoptosis induction: MMAE binds to microtubules and kills dividing cells by inhibiting cell division and inducing apoptosis

Apoptosis: Apoptosis of dividing B cells, including malignant cells, occurs

POLIVY + R-CHP modifies a standard regimen by replacing vincristine, an early-generation microtubule inhibitor, with POLIVY, a CD79b-targeted, microtubule-disrupting ADC[1,15]

ADC = antibody-drug conjugate; CD = cluster of differentiation; MMAE = monomethyl auristatin E.

Important Safety Information (continued)

Peripheral Neuropathy (continued)

The peripheral neuropathy is predominantly sensory; however, motor and sensorimotor peripheral neuropathy also occur. Monitor for symptoms of peripheral neuropathy such as hypoesthesia, hyperesthesia, paresthesia, dysesthesia, neuropathic pain, burning sensation, weakness, or gait disturbance. Patients experiencing new or worsening peripheral neuropathy may require a delay, dose reduction, or discontinuation of POLIVY.

Please see the full Prescribing Information for additional Important Safety Information.

POLARIX: Designed to evaluate PFS superiority of POLIVY® + R-CHP over R-CHOP in a head-to-head trial[1,16]

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POLARIX was a double-blind, randomized, multicenter phase 3 study of 879 patients

Eligibility criteria:
- Previously untreated LBCL
- Aged 18-80 years
- IPI score 2-5
- ECOG PS 0-2

N=879
RANDOMIZED
1:1

Every 21 days x 6 cycles

ARM A (n=440)
POLIVY* + R-CHP + placebo†

ARM B (n=439)
R-CHOP + placebo‡

Cycles 7 and 8

Rituximab

Rituximab

Key exclusion criteria: Patients with a history of indolent lymphoma, a contraindication to any component of R-CHOP, previous receipt of anthracycline agents, and known CNS involvement

Stratification factors: IPI score (2 vs 3-5), bulky disease (≥ 7.5 cm vs absence), and geographic region§

Primary endpoint:
Progression-free survival (PFS)‖

Key secondary endpoints:
Modified event-free survival (EFS),¶ complete response (CR) at EOT,# overall survival (OS)

POLIVY (1.8 mg/kg) or vincristine (1.4 mg/m^2), along with rituximab (375 mg/m^2), cyclophosphamide (750 mg/m^2), and doxorubicin (50 mg/m^2), was administered by IV infusion on Day 1 of Cycles 1-6. All patients received oral prednisone (100 mg) once daily on Days 1-5 of each of the first 6 cycles. Rituximab monotherapy (375 mg/m^2) was administered on Day 1 of Cycles 7 and 8. Each cycle was 21 days.

*Recommended dose of POLIVY is 1.8 mg/kg IV + R-CHP every 21 days for 6 cycles. †In lieu of vincristine. ‡In lieu of POLIVY. §Western Europe, US, Canada, and Australia vs Asia vs rest of world. ‖PFS was calculated in a time-to-event analysis, in which investigator-assessed disease progression, disease relapse, or death from any cause were counted as events. ¶Defined as time from randomization to the earliest occurrence of disease progression, disease relapse, death, an efficacy finding that led to non-protocol specified lymphoma treatment, or biopsy positive for residual disease. #Based on PET-CT and determined by BICR.
BICR = blinded independent central review; CNS = central nervous system; EOT = end of treatment; IV = intravenous; LBCL = large B-cell lymphoma; PET-CT = positron emission tomography and computed tomography.

Important Safety Information (continued)

Infusion-Related Reactions

POLIVY can cause severe infusion reactions. Delayed infusion-related reactions as late as 24 hours after receiving POLIVY have occurred. With premedication, 13% of patients (58/435) in POLARIX reported infusion-related reactions after the administration of POLIVY plus R-CHP. The reactions were Grade 1 in 4.4% of patients, Grade 2 in 8%, and Grade 3 in 1.1%. Symptoms occurring in ≥1% of patients included chills, dyspnea, pyrexia, pruritus, rash, and chest discomfort. Administer an antihistamine and an antipyretic prior to the administration of POLIVY, and monitor patients closely throughout the infusion. If an infusion-related reaction occurs, interrupt the infusion and institute appropriate medical management.

Please see the full Prescribing Information for additional Important Safety Information.

POLIVY® + R-CHP was studied in a range of patients with previously untreated LBCL[1]

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Patient characteristics were well-balanced across POLARIX treatment arms[1,16,17]

		POLIVY + R-CHP (n=440)	R-CHOP (n=439)
Age	>60 years, n (%)	300 (68.2)	308 (70.2)
	Median (range)	65.0 (19-80)	66.0 (19-80)
Sex, n (%)	Male	239 (54.3)	234 (53.3)
	Female	201 (45.7)	205 (46.7)
Geographic region, n (%)*	W. Europe, USA, CAN, AUS	302 (68.6)	301 (68.6)
	Asia	81 (18.4)	79 (18.0)
	Rest of world	57 (13.0)	59 (13.4)
ECOG PS, n (%)†	0-1	374 (85.0)	363 (82.7)
	2	66 (15.0)	75 (17.1)
Bulky disease, n (%)*,‡		193 (43.9)	192 (43.7)
Ann Arbor stage, n (%)§	I-II	47 (10.7)	52 (11.8)
	III-IV	393 (89.3)	387 (88.2)
IPI score, n (%)*	2	167 (38.0)	167 (38.0)
	3-5	273 (62.0)	272 (62.0)
Histologic diagnosis, n (%)	DLBCL, NOS (including GCB and ABC)	373 (84.8)	367 (83.6)
	HGBL (including NOS and DHL/THL)	43 (9.8)	50 (11.4)
	Other large B-cell lymphomas‖	24 (5.5)	22 (5.0)

DLBCL, NOS represented ~85% of LBCL cases in POLARIX, similar to real-world estimates[1,18]

*This variable was a stratification factor. †Patients had a baseline ECOG PS score of 0-2 (on a 5-point scale, with higher numbers indicating greater disability). ECOG PS was not reported for 1 patient in the R-CHOP group. ‡Bulky disease was defined as the presence of 1 or more lesions that were 7.5 cm or larger in greatest dimension. §Stages range from I to IV, with higher stages indicating more extensive disease. ‖Other large B-cell lymphomas by local diagnosis included EBV+ DLBCL, NOS, and T-cell/histiocyte-rich large B-cell lymphoma.
ABC = activated B cell; AUS = Australia; CAN = Canada; DHL = double-hit lymphoma; EBV = Epstein-Barr virus; GCB = germinal center B cell; THL = triple-hit lymphoma; USA = United States of America; W. Europe = Western Europe.

Important Safety Information (continued)

Myelosuppression

Treatment with POLIVY can cause serious or severe myelosuppression, including neutropenia, thrombocytopenia, and anemia. In POLARIX, 90% of patients treated with POLIVY plus R-CHP had primary prophylaxis with granulocyte colony-stimulating factor (G-CSF). Grade 3-4 hematologic adverse reactions included lymphopenia (44%), neutropenia (39%), febrile neutropenia (15%), anemia (14%), and thrombocytopenia (8%).

Please see the full Prescribing Information for additional Important Safety Information.

International Prognostic Index (IPI) assessment in DLBCL[12,19-21]

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- ✓ **IPI is the primary clinical tool for risk assessment in patients with 1L DLBCL**
- ✓ **IPI identifies 4 independent risk groups of patients using a combination of 5 clinical variables**

IPI Risk Factor
Ann Arbor Stage III or IV
Age > 60 years
Serum LDH > 1 x ULN
ECOG Performance Status ≥ 2
Extranodal involvement ≥ 2*

*Per Cheson, et al. 2014, extranodal involvement may include sites that have focal uptake by PET-CT, such as: spleen, liver, bone, thyroid, cutaneous, GI, bone, kidneys, pleural or pericardial effusions, ascites.

IPI Risk Group	Number of IPI Risk Factors
Low	0 or 1
Low-Intermediate	2
High-Intermediate	3
High	4 or 5

GI = gastrointestinal; LDH = lactate dehydrogenase; ULN = upper limit of normal.

Please see the full Prescribing Information for additional Important Safety Information.

PFS: A clinically meaningful endpoint in DLBCL

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- **Phase 3 trials in 1L DLBCL have been commonly designed with PFS as the primary efficacy endpoint**[13,22]
  - In the POLARIX trial, PFS was defined as the time from randomization until the first occurrence of disease progression, disease relapse, or death from any cause, whichever occurred earlier[16]
- **In oncology, PFS is a common disease-related primary endpoint**[23]
  - It can be assessed earlier than OS with fewer patients and is not confounded by subsequent therapies
  - PFS can represent direct clinical benefit*
- **PFS is recognized by the FDA as an important endpoint for drug approval in oncology**[23]
  - PFS can be used as an endpoint to support accelerated or traditional approval*
- **PFS assessment may be subject to limitations**[23]
  - Definition of PFS may vary among studies, and it may be subject to assessment bias and not always correlate with survival

*Based on specific disease, context of use, magnitude of the effect, disease setting, location of metastatic sites, available therapy, the risk-benefit relationship, and the clinical consequences of delaying or preventing progression in key disease sites (eg, delay of new lesions in the brain or spine) or delaying administration of more toxic therapies.

Important Safety Information (continued)

Myelosuppression (continued)

Monitor complete blood counts throughout treatment. Cytopenias may require a delay, dose reduction, or discontinuation of POLIVY. Administer prophylactic G-CSF for neutropenia.

Serious and Opportunistic Infections

Fatal and/or serious infections, including opportunistic infections such as sepsis, pneumonia (including *Pneumocystis jiroveci* and other fungal pneumonia), herpesvirus infection, and cytomegalovirus infection, have occurred in patients treated with POLIVY.

Please see the full Prescribing Information for additional Important Safety Information.

POLIVY® + R-CHP: Statistically significant PFS improvement vs R-CHOP[1,16]

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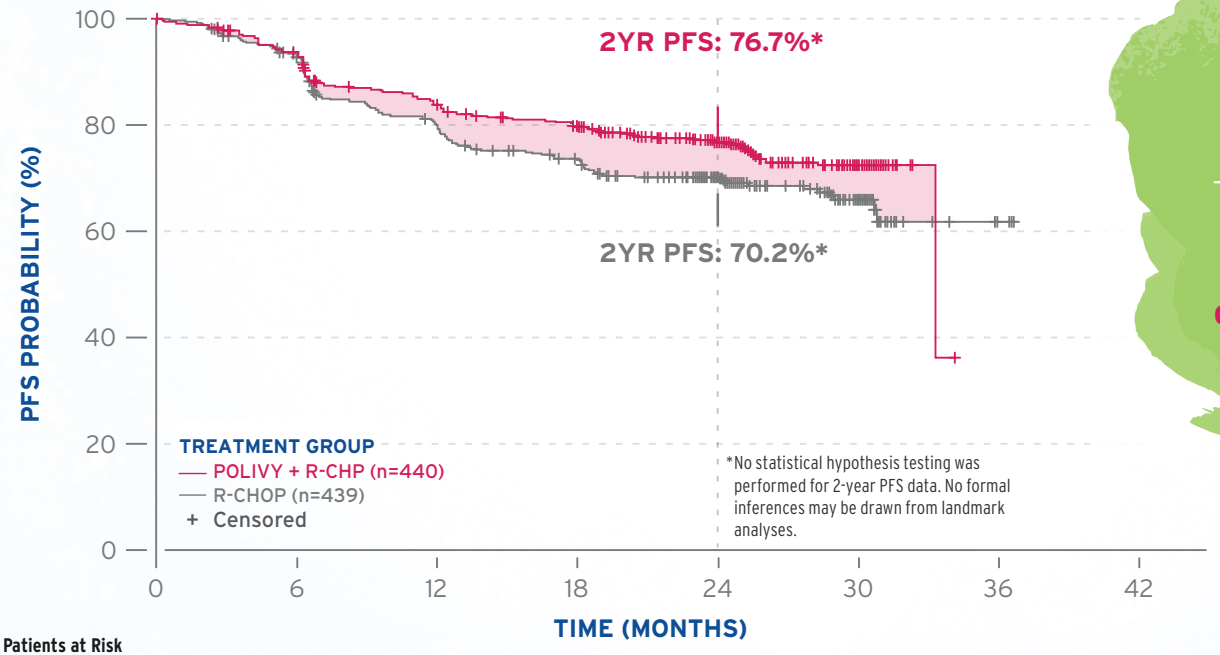
Primary analysis data after median follow-up of 24.7 months (ITT population)[1,16]



Patients at Risk								
POLIVY + R-CHP	440	404	353	327	246	78	NE	NE
R-CHOP	439	389	330	296	220	78	3	NE

Superior PFS
HR=0.73
(95% CI: 0.57, 0.95)
(p=0.0177)

27%
Reduced risk of disease progression, disease relapse, or death

- In a prespecified descriptive analysis of the largest lymphoma subgroup, DLBCL, NOS, the PFS HR was 0.75 (95% CI: 0.57, 0.99), and for the HGBL subgroup it was 0.48 (95% CI: 0.21, 1.08). No formal inferences may be drawn from these analyses
- There were insufficient data to evaluate efficacy in other large B-cell lymphomas

PFS was calculated in a time-to-event analysis, in which investigator-assessed disease progression, disease relapse, or death from any cause were counted as events.
Estimated median follow-up of 24.7 months in both arms combined.
2YR = two-year; NE = not estimable.

Important Safety Information (continued)

Serious and Opportunistic Infections (continued)

In POLARIX, Grade 3-4 infections occurred in 14% (61/435) of patients treated with POLIVY plus R-CHP and infection related deaths were reported in 1.1% of patients.

Closely monitor patients during treatment for signs of infection. Administer prophylaxis for *Pneumocystis jiroveci* pneumonia and herpesvirus. Administer prophylactic G-CSF for neutropenia as recommended.

Please see the full Prescribing Information for additional Important Safety Information.

PFS: Exploratory 5-year analysis data[24,*]

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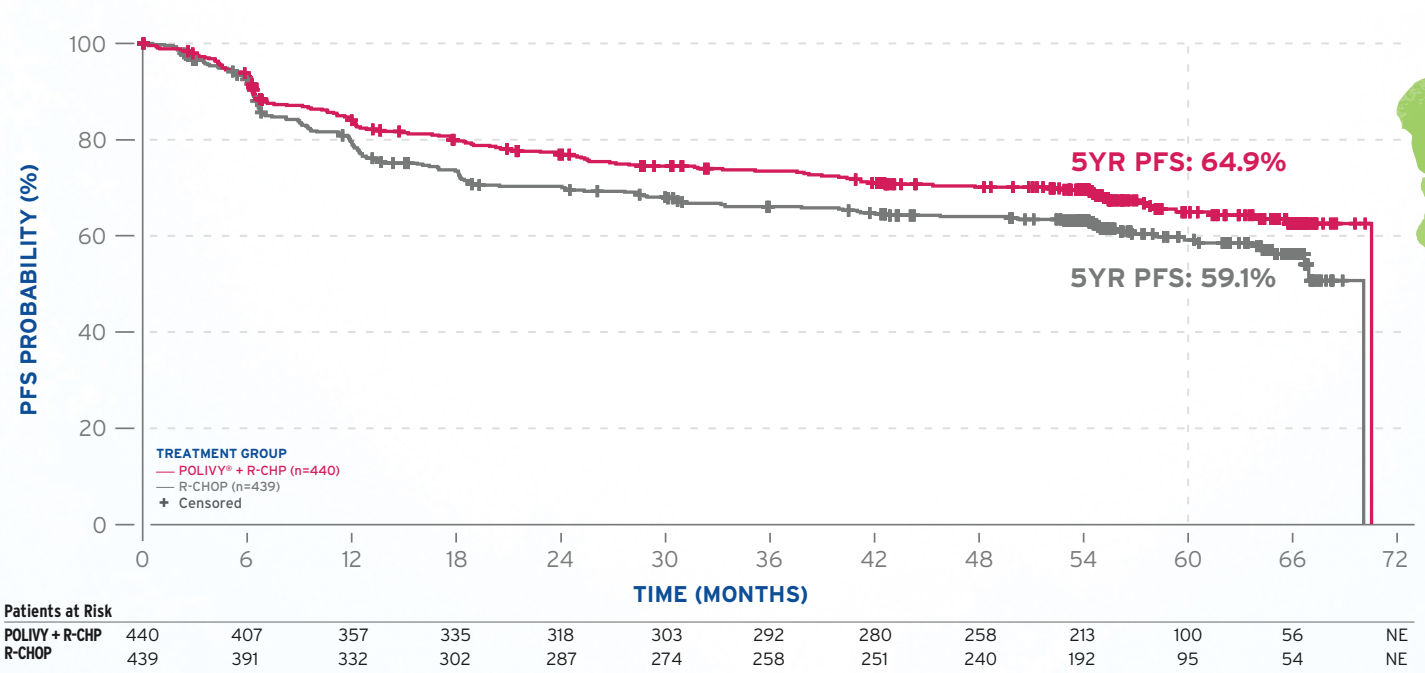
PFS after median follow-up of 54.9 months (ITT population)

Limitations: No formal inferences may be drawn from these exploratory analyses. No statistical hypothesis testing was performed for the long-term follow-up or the 5-year landmark data. The reliability of the Kaplan-Meier estimates may be affected by the small number of available patients at risk at the tail portion of the curve.



HR=0.77
(95% CI: 0.62, 0.97)

Patients at Risk													
POLIVY + R-CHP	440	407	357	335	318	303	292	280	258	213	100	56	NE
R-CHOP	439	391	332	302	287	274	258	251	240	192	95	54	NE

*Data cutoff was July 5, 2024.
5YR = five-year.

Important Safety Information (continued)

Progressive Multifocal Leukoencephalopathy (PML)

Monitor for new or worsening neurological, cognitive, or behavioral changes. Hold POLIVY and any concomitant chemotherapy if PML is suspected, and permanently discontinue if the diagnosis is confirmed.

Tumor Lysis Syndrome

POLIVY may cause tumor lysis syndrome. Patients with high tumor burden and rapidly proliferating tumors may be at increased risk of tumor lysis syndrome. Monitor closely and take appropriate measures, including tumor lysis syndrome prophylaxis.

Please see the full Prescribing Information for additional Important Safety Information.

EFS & CR: Select secondary endpoints

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Primary analysis (ITT population): Superior EFS vs R-CHOP[1,16,*]

	POLIVY® + R-CHP (n=440)	R-CHOP (n=439)
Patients with event, n (%)	112 (26)	138 (31)
HR (95% CI)	0.75 (0.58, 0.96)	
p-value[†]	0.0244	

*Modified EFS is defined as time from randomization to the earliest occurrence of disease progression, disease relapse, death, an efficacy finding that led to non-protocol specified lymphoma treatment, or biopsy positive for residual disease.
[†]Stratified log-rank test, with a two-sided significance boundary of 0.05. The hierarchical testing order was PFS and modified EFS, then CR rate and OS.

Exploratory 5-year analysis data: EFS (ITT population)[25,‡]

	POLIVY + R-CHP	R-CHOP
Patients with event, n (%)	146 (33)	172 (39)
HR (95% CI)	0.78 (0.62, 0.97)	

[‡]Data cutoff was July 5, 2024.

Limitations: No formal inferences may be drawn from these exploratory analyses. No statistical hypothesis testing was performed for the long-term follow-up data.

Primary analysis (ITT population): Objective response at EOT in patients receiving POLIVY + R-CHP vs R-CHOP[1,§]

	POLIVY + R-CHP (n=440)	R-CHOP (n=439)
Objective response rate, % (95% CI)	86 (82, 89)	84 (80, 87)
CR rate, %	78 (74, 82)	74 (70, 78)
Difference in CR rate, % (95% CI)	3.9 (-1.9, 9.7)	
p-value[‖]	0.1557	

[§]By BICR, per 2014 Lugano response criteria.
[‖]Cochran-Mantel-Haenszel chi-squared test, with a two-sided significance boundary of 0.01.

CR = complete response.

Important Safety Information (continued)

Hepatotoxicity

Serious cases of hepatotoxicity that were consistent with hepatocellular injury, including elevations of transaminases and/or bilirubin, have occurred in patients treated with POLIVY.

In recipients of POLIVY plus R-CHP, Grade 3–4 elevation of ALT and AST developed in 1.4% and 0.7% of patients, respectively.

Preexisting liver disease, elevated baseline liver enzymes, and concomitant medications may increase the risk of hepatotoxicity. Monitor liver enzymes and bilirubin level.

Please see the full Prescribing Information for additional Important Safety Information.

OS: Secondary endpoint[1,26]

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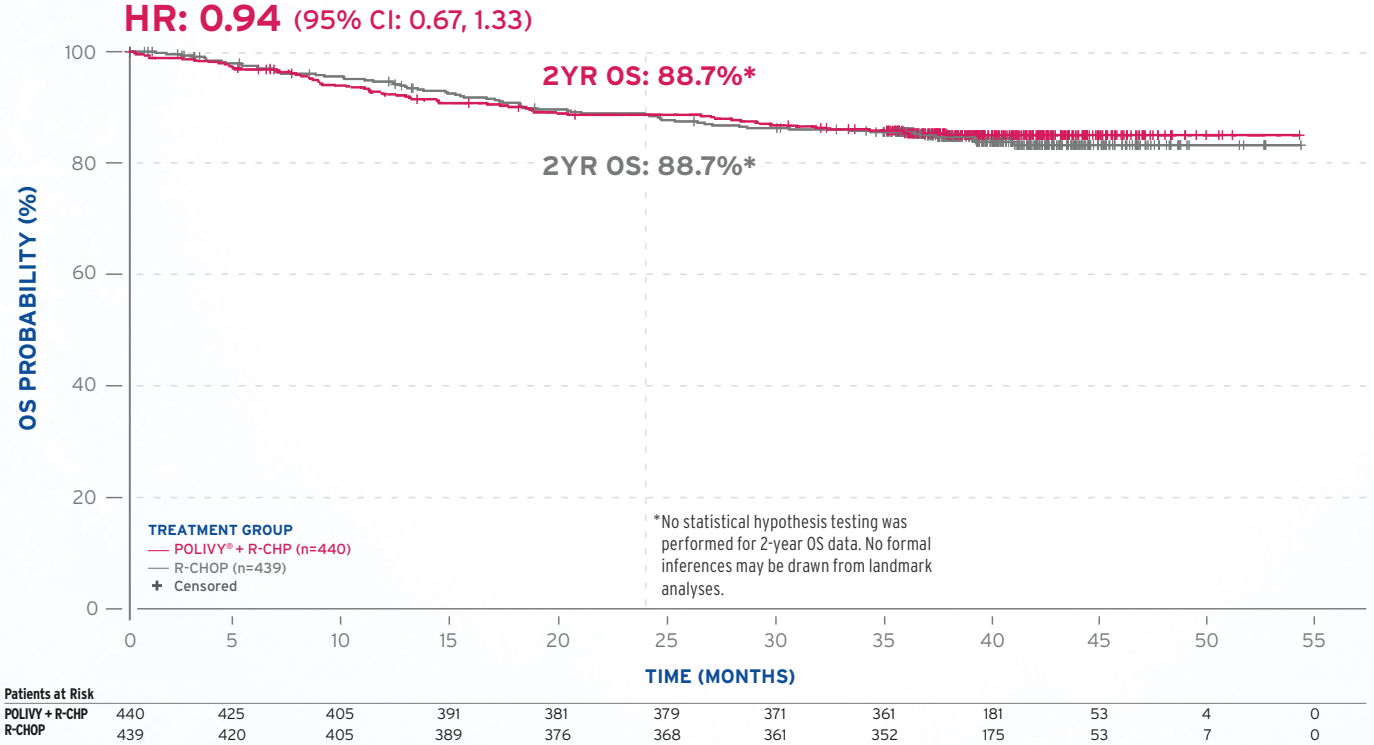
Prespecified final OS analysis after a median follow-up of 39.7 months (ITT population)



- With an estimated median follow-up of 39.7 months (3.3 years), the prespecified final analysis of OS showed no statistically significant difference, with an HR of 0.94 (95% CI: 0.67, 1.33)
  - 64/440 patients (14.5%) in the POLIVY + R-CHP arm and 67/439 patients (15.3%) in the R-CHOP arm had an OS event
- In a descriptive analysis, the OS HR in patients with DLBCL, NOS, was 1.02 (95% CI: 0.70, 1.49), and in patients with HGBL it was 0.42 (95% CI: 0.15, 1.19)
  - No formal inferences may be drawn from this analysis

Important Safety Information (continued)

Embryo-Fetal Toxicity

Based on the mechanism of action and findings from animal studies, POLIVY can cause fetal harm when administered to a pregnant woman. When administered to rats, the small molecule component of POLIVY, monomethyl auristatin E, caused adverse developmental outcomes, including embryo-fetal mortality and structural abnormalities, at exposures below those occurring clinically at the recommended dose.

Please see the full Prescribing Information for additional Important Safety Information.

OS: Exploratory 5-year analysis data[24]

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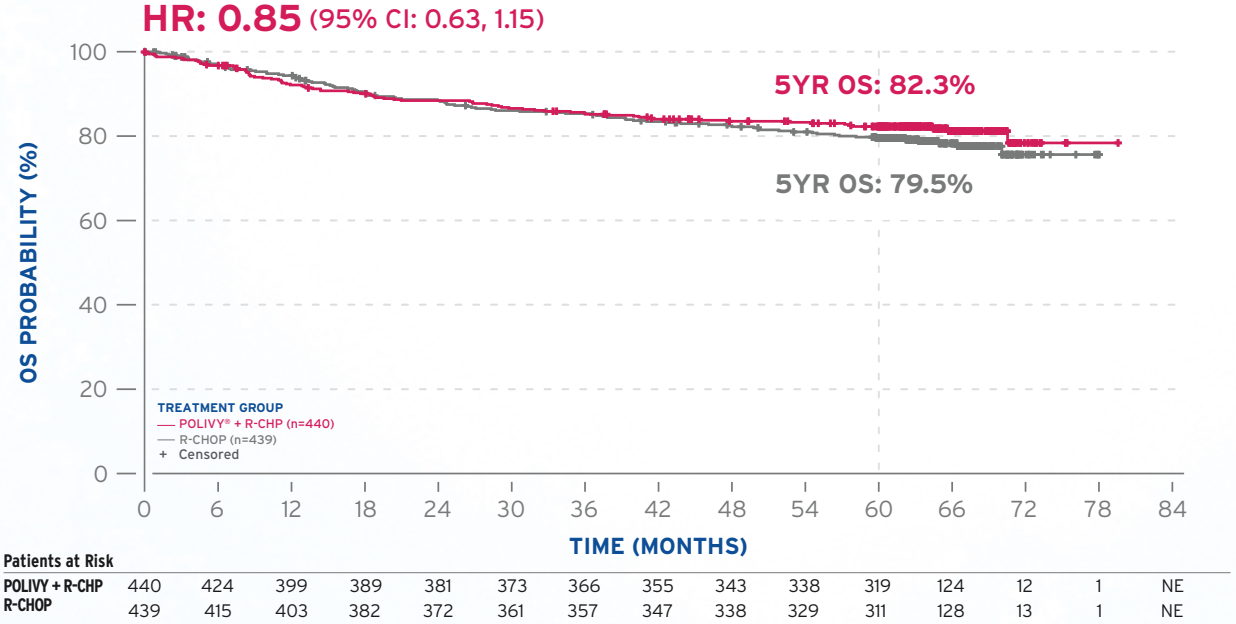
OS after median follow-up of 64.1 months (ITT population)*

Limitations: OS data were not mature at the time of data cutoff, and the median has not been reached. No formal inferences may be drawn from these exploratory analyses. No statistical hypothesis testing was performed for the long-term follow-up or 5-year landmark data. The reliability of the Kaplan-Meier estimates may be affected by the small number of available patients at risk at the tail portion of the curve.



Patients at Risk															
POLIVY + R-CHP	440	424	399	389	381	373	366	355	343	338	319	124	12	1	NE
R-CHOP	439	415	403	382	372	361	357	347	338	329	311	128	13	1	NE

*Data cutoff was July 5, 2024.

- In the exploratory long-term follow-up (median follow-up of 64.1 months), 79/440 patients (18.0%) in the POLIVY + R-CHP arm and 91/439 patients (20.7%) in the R-CHOP arm had an OS event. In addition to the known deaths, there were 2 patients (1 in the POLIVY + R-CHP arm and 1 in the R-CHOP arm) who died due to an unknown cause and an unknown death date; these were not counted as death events in the OS analysis

Important Safety Information (continued)

Embryo-Fetal Toxicity (continued)

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with POLIVY and for 3 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with POLIVY and for 5 months after the last dose.

Please see the full Prescribing Information for additional Important Safety Information.

Subsequent lymphoma therapy: Exploratory 5-year analysis data[17,24]

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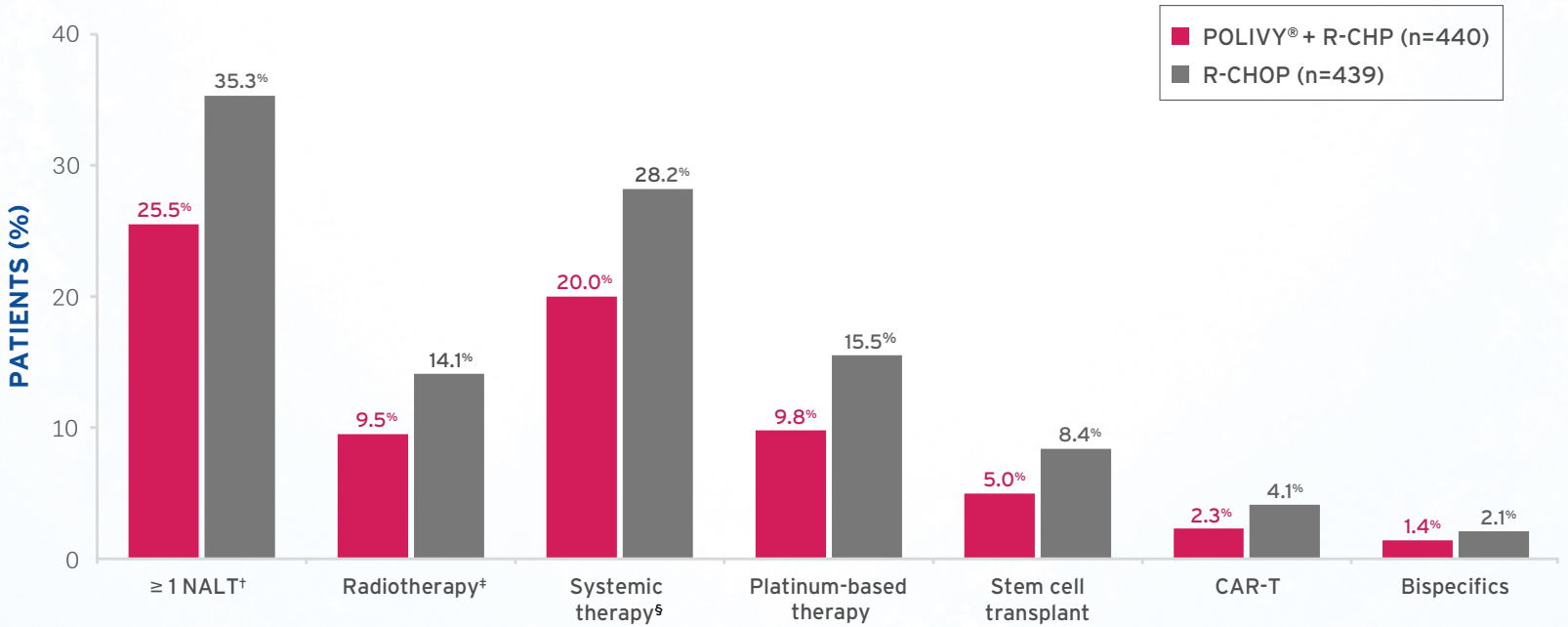
Patients receiving subsequent lymphoma therapy (ITT population)*

Limitations: No formal inferences may be drawn from these 5-year observational data. These data on subsequent treatment were collected per protocol, but no formal analyses were conducted. POLARIX was a global trial: availability of subsequent therapy options and local practice patterns varied. NALT is dependent on the preferences of the prescribers and patients.



*Data cutoff was July 5, 2024.
†Subsequent lymphoma treatment was defined as NALT and does not include R-CHOP or POLIVY + R-CHP.
‡Including preplanned and unplanned.
§Includes any monotherapy, multidrug, or cell-based.
CAR-T = chimeric antigen receptor T-cell therapy; NALT = new anti-lymphoma therapy.

Important Safety Information (continued)

The Most Common Adverse Reactions

The most common adverse reactions (≥20%), excluding laboratory abnormalities, are peripheral neuropathy, nausea, fatigue, diarrhea, constipation, alopecia, and mucositis. Grade 3 to 4 laboratory abnormalities (≥10%) are lymphopenia, neutropenia, hyperuricemia, and anemia.

Please see the full Prescribing Information for additional Important Safety Information.

The majority of adverse reactions ≥ 10% were generally comparable across treatment arms[1,*]

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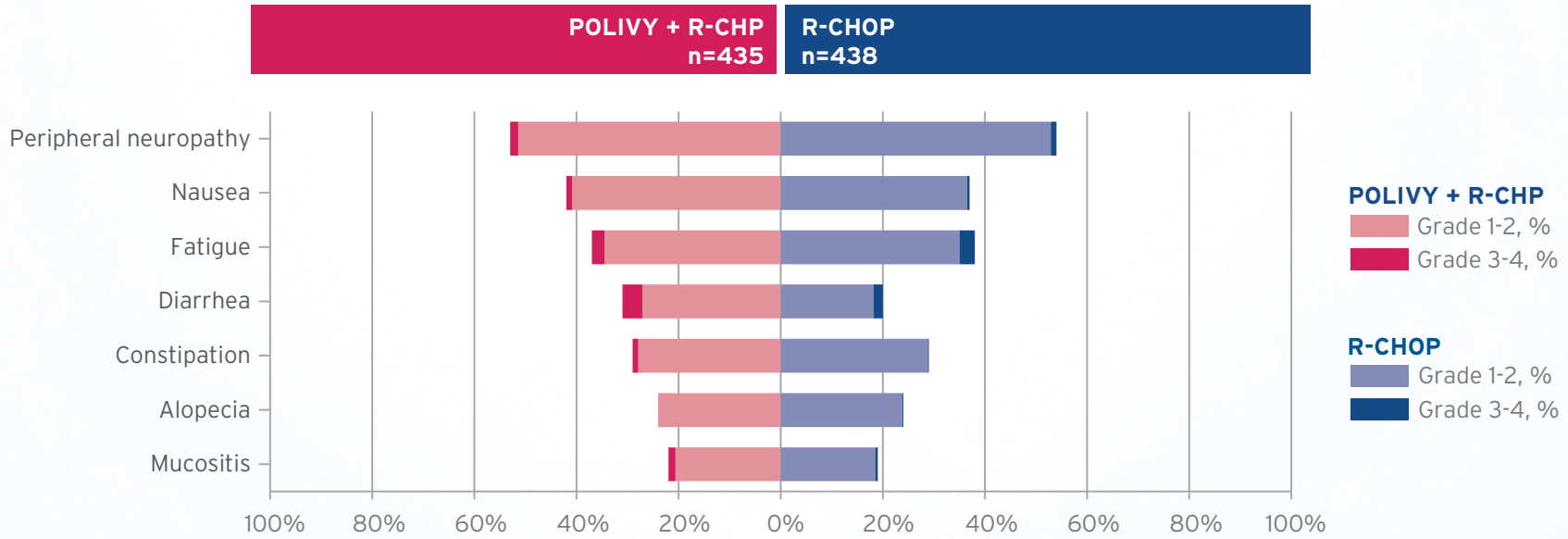
Primary analysis data

*Adverse reactions with ≥ 5% difference in all grades or grade ≥ 3 include (POLIVY® + R-CHP vs R-CHOP): diarrhea (all grades: 31% vs 20%; grade ≥ 3: 3.9% vs 1.8%), febrile neutropenia (all grades and grade ≥ 3: 15% vs 9%), and nausea (all grades: 42% vs 37%; grade ≥ 3: 1.1% vs 0.5%).

Most common adverse reactions in ≥ 20% of patients



- The rates of peripheral neuropathy between the POLIVY + R-CHP vs R-CHOP arms were 53% vs 54%, respectively[1]
- The rates of febrile neutropenia between the POLIVY + R-CHP vs R-CHOP arms were 15% and 9%, respectively (for all grades and grade ≥ 3)[1]
- The rates of grade 3-4 infections were comparable between POLIVY + R-CHP vs R-CHOP arms (14% vs 11%)[27]
- Serious ARs occurred in 34% of patients who received POLIVY + R-CHP vs 30.6% of patients who received R-CHOP[1,16]
- Serious ARs in ≥ 5% of patients who received POLIVY + R-CHP included febrile neutropenia and pneumonia[1]

AR = adverse reaction.

- Fatal ARs reported within 90 days of last treatment occurred in 3% of patients who received POLIVY + R-CHP vs 2.3% of patients who received R-CHOP. These were primarily from infection, including pneumonia (0.9% and 0.7%, respectively) and sepsis (0.2% and 0.7%, respectively)[1,16,17]
- New or worsening Grade 3 to 4 laboratory abnormalities observed in ≥ 10% of patients were lymphopenia, neutropenia, hyperuricemia, and anemia[1]

Exploratory 5-year analysis data[24]

Safety profile was consistent with the primary analysis.

Limitations: No formal inferences may be drawn from this analysis.

Please see the full Prescribing Information for additional Important Safety Information.

The majority of adverse reactions ≥ 10% were generally comparable across treatment arms (cont'd)[1,*]

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Primary analysis data (cont'd)

*Adverse reactions with ≥ 5% difference in all grades or grade ≥ 3 include (POLIVY® + R-CHP vs R-CHOP): diarrhea (all grades: 31% vs 20%; grade ≥ 3: 3.9% vs 1.8%), febrile neutropenia (all grades and grade ≥ 3: 15% vs 9%), and nausea (all grades: 42% vs 37%; grade ≥ 3: 1.1% vs 0.5%).

ARs (≥ 10%) by Body System	POLIVY + R-CHP (n=435)		R-CHOP (n=438)	
	All Grades (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Blood and lymphatic system disorders†				
Lymphopenia	80	44	77	44
Anemia	68	14	67	11
Neutropenia	60	39	60	42
Thrombocytopenia	32	8	33	6
Febrile neutropenia‡	15	15	9	9
Investigations†				
Creatinine increased	66	0.7	64	0.9
Aspartate aminotransferase increased	26	0.7	23	1.1
Alanine aminotransferase increased	25	1.4	27	0.5
Alkaline phosphatase increased	23	0	22	0.5
Uric acid increased	19	18	17	16
Weight decreased	13	0.9	12	0.2
Nervous system disorders				
Peripheral neuropathy§,‖	53	1.6	54	1.1
Altered taste	14	0	16	0
Headache	13	0.2	14	0.9

The table includes a combination of grouped and ungrouped terms. Events were graded using NCI CTCAE version 4.0.
†Laboratory values are based on integrated analysis of laboratory and adverse reaction data. Reported investigations exclude electrolytes.
‡Febrile neutropenia includes febrile neutropenia, febrile bone marrow aplasia, and neutropenic sepsis.
§At last assessment, peripheral neuropathy was unresolved in 42% in the POLIVY + R-CHP arm and in 33% in the R-CHOP arm.
‖Peripheral neuropathy includes all terms containing "neuropathy," neuralgia, dysesthesia, paresthesia, hypoesthesia, peroneal nerve palsy, hypotonia, hyporeflexia, neuromyopathy, and hyperesthesia.
NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events.

Additional peripheral neuropathy results

- 53% of patients treated with POLIVY + R-CHP reported new or worsening peripheral neuropathy[1,16]
  - The median time to onset was 2.3 months with POLIVY + R-CHP vs 1.9 months with R-CHOP
- Peripheral neuropathy resulting in treatment discontinuation or dose reduction occurred in 0.7% and 4% of patients receiving POLIVY + R-CHP, respectively[1]
- At last assessment, peripheral neuropathy was resolved in 58% of patients in the POLIVY + R-CHP arm at a median of 4 months and in 67% of patients in the R-CHOP arm at a median of 4.6 months[1,27]

Please see the full Prescribing Information for additional Important Safety Information.

The majority of adverse reactions ≥ 10% were generally comparable across treatment arms (cont'd)[1,*]

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Primary analysis data (cont'd)

*Adverse reactions with ≥ 5% difference in all grades or grade ≥ 3 include (POLIVY® + R-CHP vs R-CHOP): diarrhea (all grades: 31% vs 20%; grade ≥ 3: 3.9% vs 1.8%), febrile neutropenia (all grades and grade ≥ 3: 15% vs 9%), and nausea (all grades: 42% vs 37%; grade ≥ 3: 1.1% vs 0.5%).

ARs (≥ 10%) by Body System	POLIVY + R-CHP (n=435)		R-CHOP (n=438)	
	All Grades (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Gastrointestinal disorders				
Nausea	42	1.1	37	0.5
Diarrhea	31	3.9	20	1.8
Constipation	29	1.1	29	0.2
Mucositis†	22	1.4	19	0.5
Abdominal pain‡	16	1.1	14	1.6
Vomiting	15	1.1	14	0.7
General disorders				
Fatigue	37	2.5	38	3.0
Pyrexia	16	1.4	13	0
Edema§	14	0.5	11	0.2
Infusion-related reaction‖	13	1.1	16	1.6
Skin and subcutaneous tissue disorders				
Alopecia	24	0	24	0.2
Rash¶	13	0.7	11	0
Musculoskeletal disorders				
Musculoskeletal pain#	19	0.5	21	1.8

The table includes a combination of grouped and ungrouped terms. Events were graded using NCI CTCAE version 4.0.
†Mucositis includes stomatitis, oropharyngeal pain, mucosal inflammation, mouth ulceration, oral pain, oropharyngeal discomfort, aphthous ulcer, odynophagia, oral discomfort, tongue blistering, and tongue ulceration.
‡Abdominal pain includes abdominal pain, abdominal discomfort, gastrointestinal pain, epigastric discomfort, and related terms.
§Edema includes edema, face edema, swelling face, edema peripheral, fluid overload, fluid retention, pulmonary edema, peripheral swelling, and swelling.
‖Infusion-related reaction is reflective of the combination regimen due to same-day administration.
¶Rash includes rash, dermatitis, and related terms.
#Musculoskeletal pain includes musculoskeletal pain, back pain, musculoskeletal chest pain, neck pain, myalgia, and bone pain.

Please see the full Prescribing Information for additional Important Safety Information.

The majority of adverse reactions ≥ 10% were generally comparable across treatment arms (cont'd)[1,*]

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Primary analysis data (cont'd)

*Adverse reactions with ≥ 5% difference in all grades or grade ≥ 3 include (POLIVY® + R-CHP vs R-CHOP): diarrhea (all grades: 31% vs 20%; grade ≥ 3: 3.9% vs 1.8%), febrile neutropenia (all grades and grade ≥ 3: 15% vs 9%), and nausea (all grades: 42% vs 37%; grade ≥ 3: 1.1% vs 0.5%).

ARs (≥ 10%) by Body System	POLIVY + R-CHP (n=435)		R-CHOP (n=438)	
	All Grades (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Infections				
Upper respiratory tract infection†	17	0.5	16	0.5
Metabolism and nutrition disorders				
Decreased appetite	17	1.1	14	0.7
Respiratory disorders				
Cough	15	0	14	0
Dyspnea	13	0.9	10	0.9

Other clinically relevant adverse reactions in < 10% of patients who received POLIVY + R-CHP included pneumonia, herpesvirus infection, sepsis, cytomegalovirus infection, tumor lysis syndrome, renal insufficiency, and pneumonitis.

The table includes a combination of grouped and ungrouped terms. Events were graded using NCI CTCAE version 4.0.
†Upper respiratory tract infection includes sinusitis, laryngitis, pharyngitis, nasopharyngitis, rhinitis, and specific infections.

Dose reductions and discontinuation rates with POLIVY + R-CHP vs R-CHOP[1,16,27]

	POLIVY (n=435)	Vincristine (n=438)
ARs leading to dose reduction	6%	10.3%
ARs leading to permanent discontinuation	4.4%	5%
ARs leading to dose interruption	18%	15.3%

More patients received 6 cycles of POLIVY vs vincristine (92% vs 89%)[16]

Please see the full Prescribing Information for additional Important Safety Information.

The POLIVY® + R-CHP regimen replaces vincristine with POLIVY, maintaining the familiar R-CHP dosing schedule[1]

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POLIVY + R-CHP is administered as a fixed duration therapy over 6, 21-day cycles

DAY 1

Can be administered in any order for each cycle after prednisone:

- **Prednisone**
- **POLIVY 1.8 mg/kg IV**
- **Rituximab product**
- **Cyclophosphamide**
- **Doxorubicin**

DAY 2-5

Prednisone

DAY 6-21

BREAK

REPEAT FOR TOTAL OF 6 CYCLES

Refer to the product information of each agent for more information

If the previous cycle of POLIVY was well-tolerated, the infusion time of the subsequent cycle may be reduced

CYCLE 1

90 min of infusion and monitoring followed by at least 90 min of monitoring

SUBSEQUENT CYCLES

30 min of infusion and monitoring followed by at least 30 min of monitoring if the previous infusion was well-tolerated

- Patients should be monitored during the infusion and after the infusion is finished
- If a planned dose of POLIVY is missed, administer as soon as possible. Adjust the schedule of administration to maintain a 21-day interval between doses
- See Dose Modifications on pages 22-23 for management guidelines for peripheral neuropathy, infusion-related reactions, and myelosuppression

Genentech is here to support the incorporation of POLIVY + R-CHP into your practice; contact your local representative for an in-service

Important Safety Information (continued)

Lactation

Advise women not to breastfeed during treatment with POLIVY and for 2 months after the last dose.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

Please see the full Prescribing Information for additional Important Safety Information.

POLIVY® + R-CHP: Recommended prophylactic medications and administration requirements

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Recommended prophylactic medications for POLIVY + R-CHP[1]

✓ **Potential infusion-related reactions**

- If not already premedicated for a rituximab product, administer an antihistamine and antipyretic at least 30-60 minutes prior to POLIVY

✓ **Pneumocystis pneumonia and herpesvirus**

- Administer prophylaxis for *Pneumocystis jiroveci* pneumonia and herpesvirus throughout treatment with POLIVY

✓ **Neutropenia**

- Administer prophylactic granulocyte colony-stimulating factor (G-CSF) for neutropenia in patients receiving POLIVY + R-CHP

✓ **Tumor lysis syndrome**

- Administer tumor lysis syndrome prophylaxis for patients at increased risk

Administration requirements for POLIVY + R-CHP[1]

- Administer POLIVY as an IV infusion only
- POLIVY must be administered using a dedicated infusion line equipped with a sterile, non-pyrogenic, low-protein binding in-line or add-on filter (0.2- or 0.22-micron pore size) and a catheter
- Do not mix POLIVY with or administer as an infusion with other drugs
- See full Prescribing Information for complete dosing and administration requirements

Please see the full Prescribing Information for additional Important Safety Information.

Adverse reaction management with dose modification

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POLIVY® dose modification for peripheral neuropathy[1]

Adverse reaction	Grade	Dose modification*
Peripheral sensory neuropathy	Grade 1	None
	Grade 2	If resolves to Grade 1 or lower before the next scheduled dose, resume at the same dose level. If Grade 2 persists at the next scheduled dose, reduce one dose level.
	Grade 3	Withhold until Grade 2 or lower and reduce one dose level.
	Grade 4	Permanently discontinue.
Peripheral motor neuropathy	Grade 1	None
	Grade 2 or 3	Withhold until Grade 1 or lower and reduce one dose level.
	Grade 4	Permanently discontinue.
R-CHP should be continued if POLIVY is withheld. If there is concurrent sensory and motor neuropathy, follow the guidance for the most severe neuropathy. If the grade of sensory and motor neuropathy are the same, follow the guidance for motor neuropathy.		

*Starting dose for POLIVY is 1.8 mg/kg. First dose reduction level is 1.4 mg/kg. Second dose reduction level is 1 mg/kg. No further dose reduction is recommended beyond 1 mg/kg. If further reduction is needed, discontinue POLIVY.

Please see the full Prescribing Information for additional Important Safety Information.

Adverse reaction management with dose modification (cont'd)

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POLIVY® dose modification for IRRs[1]

Adverse reaction	Grade	Dose modification*
Infusion-related reactions	Grade 1-3	Interrupt POLIVY infusion and give supportive treatment. For the first instance of Grade 3 wheezing, bronchospasm, or generalized urticaria, permanently discontinue POLIVY. For recurrent Grade 2 wheezing or urticaria, or for recurrence of any Grade 3 symptoms, permanently discontinue POLIVY. Otherwise, upon complete resolution of symptoms, infusion may be resumed at 50% of the rate achieved prior to interruption. In the absence of infusion-related symptoms, the rate of infusion may be escalated in increments of 50 mg/hour every 30 minutes. For the next cycle, infuse POLIVY over 90 minutes. If no infusion-related reaction occurs, subsequent infusions may be administered over 30 minutes. Administer premedication for all cycles.
Infusion-related reactions	Grade 4	Stop POLIVY infusion immediately. Give supportive treatment. Discontinue POLIVY.

POLIVY dose modification for myelosuppression[1]

Adverse reaction	Grade	Dose modification*
Neutropenia†,‡	Grade 3-4	Hold all treatment until ANC recovers to greater than or equal to 1,000/microliter. Consider therapeutic G-CSF if neutropenia occurs after prophylactic G-CSF. If ANC recovers to greater than or equal to 1,000/microliter on or before Day 7, resume all treatment without any dose reductions. If ANC recovers to greater than or equal to 1,000/microliter after Day 7: • Resume all treatment • Administer prophylactic G-CSF in next cycle. If G-CSF was already given, consider a dose reduction of POLIVY
Thrombocytopenia†,‡	Grade 3-4	Hold all treatment until platelets recover to greater than or equal to 75,000/microliter. If platelets recover to greater than or equal to 75,000/microliter on or before Day 7, resume all treatment without any dose reductions. If platelets recover to greater than or equal to 75,000/microliter after Day 7: • Resume all treatment and consider a dose reduction of POLIVY

Toxicity graded per NCI CTCAE version 4.0.
*Starting dose for POLIVY is 1.8 mg/kg. First dose reduction level is 1.4 mg/kg. Second dose reduction level is 1 mg/kg. No further dose reduction is recommended beyond 1 mg/kg. If further reduction is needed, discontinue POLIVY.
†Severity on Day 1 of any cycle.
‡If primary cause is lymphoma, dosage delay or reduction may not be needed.
ANC = absolute neutrophil count; IRR = infusion-related reaction.

Please see the full Prescribing Information for additional Important Safety Information.

Genentech patient support services are here to help patients and practices after POLIVY® has been prescribed

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Support for Patients

Financial assistance is available to help eligible patients who have been prescribed POLIVY, regardless of their situation

- ✓ If eligible commercially insured patients need assistance with their out-of-pocket costs, the Genentech Oncology Co-pay Assistance Program may help*
- ✓ If eligible publicly or commercially insured patients have difficulty paying for their co-pay, co-insurance, or other out-of-pocket costs, Genentech Access Solutions can refer them to an independent co-pay assistance foundation supporting their diagnosis†
- ✓ If patients don't have health insurance coverage or have financial concerns and meet eligibility criteria, they may be able to get free medicine from the Genentech Patient Foundation‡

*Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their Genentech medicine. Patients must be taking the Genentech medicine for an FDA-approved indication. Please visit the Co-pay Program website for the full list of Terms and Conditions. †Independent co-pay assistance foundations have their own rules for eligibility. Genentech has no involvement or influence in independent foundation decision-making or eligibility criteria and does not know if a foundation will be able to help your patient. We can only refer your patient to a foundation that supports their disease state. Genentech does not endorse or show preference for any particular foundation. The foundations to which we refer your patient may not be the only ones that might be able to help. ‡To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements. Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

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Please see the full Prescribing Information for additional Important Safety Information.

Genentech patient support services are here to help patients and practices after POLIVY® has been prescribed (cont'd)

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Support for Practices

Genentech Access Solutions provides helpful access and reimbursement support after POLIVY has been prescribed. We can help your patients and practice by providing*:

- ✓ Benefits investigations (BIs)
- ✓ Prior authorization (PA) resources
- ✓ Resources for denials and appeals
- ✓ Sample coding information
- ✓ Clinical education and in-service presentations
- ✓ Information about authorized specialty pharmacies (SPs) and specialty distributors

*The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech makes no representation or guarantee concerning coverage or reimbursement for any service or item.

For more information contact your local Genentech representative, visit POLIVY-HCP.com, or call (888) 249-4918

Please see the full Prescribing Information for additional Important Safety Information.

POLIVY® + R-CHP: The first FDA-approved treatment for 1L DLBCL since 2006[1,14]

- POLIVY + R-CHP demonstrated superior PFS vs R-CHOP in the ITT population (HR [95% CI]: 0.73 [0.57, 0.95], p=0.0177)[1]
- The safety of POLIVY + R-CHP vs R-CHOP was evaluated in a head-to-head trial of 873 patients[1]
- The POLIVY + R-CHP regimen replaces vincristine with POLIVY, maintaining the familiar R-CHP dosing schedule[1,14]

POLARIX: A double-blind, placebo-controlled, randomized, multicenter phase 3 study that evaluated the efficacy and safety of POLIVY + R-CHP (n=440) vs R-CHOP (n=439).[1]
Eligible patients had DLBCL, NOS, HGBL, or other large B-cell lymphoma (including EBV+ DLBCL, NOS, and T-cell/histiocyte-rich LBCL), and IPI ≥ 2. Primary endpoint was investigator-assessed PFS.[1]

Indication

POLIVY in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater.

Select Important Safety Information

Serious and sometimes fatal adverse reactions can occur with POLIVY treatment. Peripheral neuropathy, infusion-related reactions, myelosuppression, serious and opportunistic infections, progressive multifocal leukoencephalopathy (PML), tumor lysis syndrome, hepatotoxicity, and embryo-fetal toxicity can occur with POLIVY treatment.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

Please see the full Prescribing Information for additional Important Safety Information.

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INJECTION FOR INTRAVENOUS USE 30 MG | 140 MG