MONJUVI
tafasitamab-cxix

rituximab & lenalidomide

MONJUVI + R2—the first and only CD19- and CD20-targeted immunotherapy combination approved for 2L+ follicular lymphoma patients[1]

MONJUVI + R2 is a **12-cycle fixed duration treatment** that can be administered in a local outpatient setting **without hospitalization required**[1]

NCCN CATEGORY 1

National Comprehensive Cancer Network® (NCCN®) recommends as an NCCN Category 1 Preferred Treatment Option

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) **recommend tafasitamab-cxix (MONJUVI) in combination with rituximab and lenalidomide as a Category 1 preferred second-line** or subsequent therapy option (if not previously used) for FL after ≥1 prior systemic therapy, including an anti-CD20 mAb.[2]

NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

inMIND was a Phase 3, double-blind, international, multicenter study of 548 adult patients with relapsed or refractory FL Grade 1, 2, or 3a after at least 1 systemic therapy, including an anti-CD20 antibody. Patients were randomized 1:1 to receive 12 cycles of MONJUVI + R2 or placebo + R2. The primary endpoint was investigator-assessed PFS using the Lugano criteria.[1,3]

R2=rituximab and lenalidomide; 2L+=second-line plus; PFS=progression-free survival.

INDICATIONS & USAGE

MONJUVI (tafasitamab-cxix), in combination with lenalidomide and rituximab, is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).

Limitations of Use: MONJUVI is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Infusion-Related Reactions

MONJUVI (tafasitamab-cxix) can cause infusion-related reactions (IRRs).

In inMIND, infusion-related reactions occurred in 16% of the 274 patients with FL who received MONJUVI in combination with lenalidomide and rituximab. Signs and symptoms included fever, chills, rash, flushing, dyspnea, and hypertension. These reactions were generally managed with temporary interruption of the infusion and/or with supportive medication.

Premedicate patients prior to starting MONJUVI infusion. Monitor patients frequently during infusion. Based on the severity of the infusion-related reaction, interrupt or discontinue MONJUVI. Institute appropriate medical management.

Please see additional Important Safety Information throughout and the full Prescribing Information.

MONJUVI®
tafasitamab-cxix | 200mg
for injection, for intravenous use

MONJUVI + R2 was studied in a 2L+ FL broad patient population that included tough-to-treat patients as well as those who relapsed later in their disease[1,4-6]

- In inMIND, **68%** were **non-POD24 (late relapse)** and **32%** were **POD24 (early relapse)**[3]
- Tough-to-treat patients included **83% high tumor burden** (met at least 1 GELF criteria) and **43% refractory to prior anti-CD20 therapy**[1,3]

Baseline Patient Characteristics[3,7]

Select Baseline Characteristic		MONJUVI + R2 (n=273)	Placebo + R2 (n=275)
Median age, years (range)		64 (36, 88)	64 (31, 85)
Sex, %	Male	55	54
	Female	45	46
Race, %*	White	80	80
	Asian	15	15
	Other races	1	2
FL grade at trial entry, %†	Grade 1	22	19
	Grade 2	52	55
	Grade 3a	25	26
At least 1 GELF criteria at baseline, %		81	84
POD24 (early relapse), %		31	32
Non-POD24 (late relapse), %		69	68
Median number of prior lines of therapy (range)		1 (1, 7)	1 (1, 10)
Refractory to most recent prior therapy, %		41	35
Refractory to prior anti-CD20 therapy, %		43	42

- Refractory lymphoma was defined as achieved less than PR to the last treatment or achieved a CR or PR that lasted <6 months[8]
- POD24 was defined as progression of disease within 24 months after initial diagnosis[1]

FL=follicular lymphoma; GELF=Groupe d'Etude des Lymphomes Folliculaires; POD24=progression of disease within 24 months after initial diagnosis; PR=partial response; CR=complete response.

*Race was not reported in 4% (n=11) of patients in the MONJUVI + R2 arm and 4% (n=10) of patients in the placebo + R2 arm.[3]
†FL grade at trial entry was not reported for 3 patients in the MONJUVI + R2 arm and 1 patient in the placebo + R2 arm.[7]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

Myelosuppression

MONJUVI can cause serious or severe myelosuppression, including neutropenia, lymphopenia, thrombocytopenia, and anemia.

In inMIND, among 274 patients with FL who received MONJUVI in combination with lenalidomide and rituximab, new or worsening Grade 3 or 4 cytopenias included decreased neutrophils in 48% (Grade 4, 19%), decreased lymphocytes in 22% (Grade 4, 1.8%), decreased hemoglobin in 9%, and decreased platelets in 8% (Grade 4, 4%). Febrile neutropenia occurred in 4.4%.

Monitor complete blood counts (CBCs) prior to administration of each treatment cycle and throughout treatment. Monitor patients with neutropenia for signs of infection. Consider granulocyte colony-stimulating factor (G-CSF) administration. Withhold MONJUVI based on the severity of the adverse reaction. Refer to the lenalidomide prescribing information for dosage modifications.

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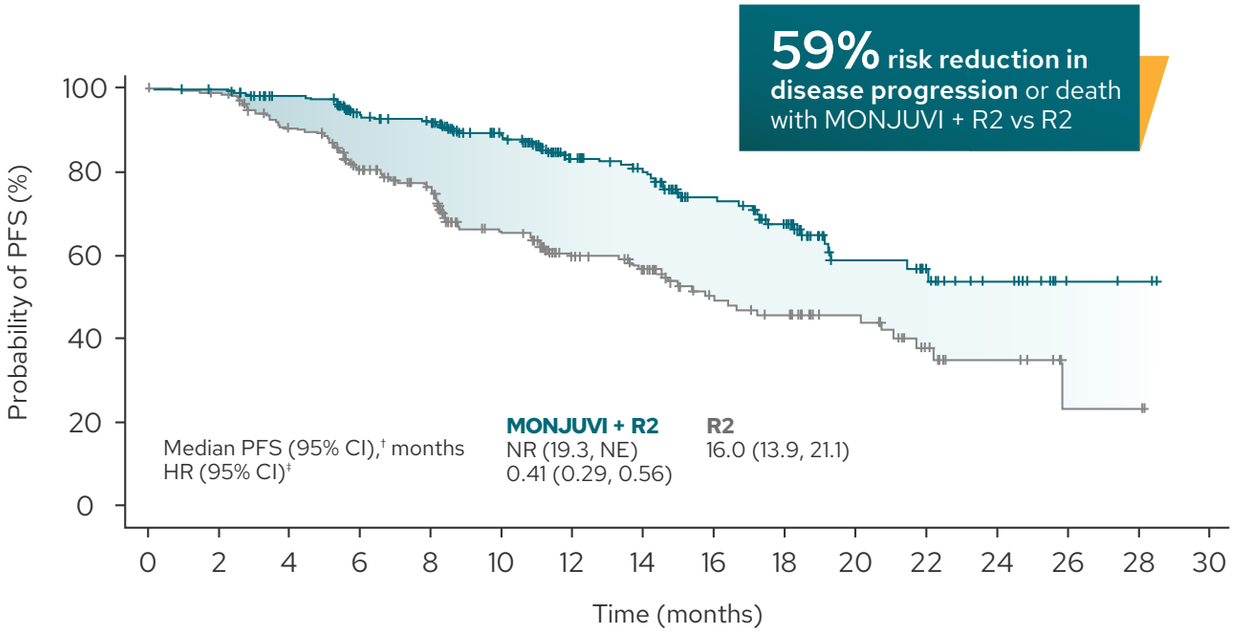
59% risk reduction in disease progression or death with MONJUVI + R2 as assessed by IRC[3]

IRC-Assessed PFS (Secondary Endpoint)

Median PFS was not reached with MONJUVI + R2 vs 16 months with R2[3]*



Number of patients at risk

MONJUVI + R2	273	260	246	210	200	162	113	98	72	58	28	20	12	3	2	0
R2	275	260	230	193	170	120	79	67	44	38	26	15	8	2	2	0

*PFS by IRC assessment was not formally tested for statistical significance.

Investigator-Assessed PFS (Primary Endpoint)

- Median PFS† was **22.4 months** (95% CI: 19.2, NE) with MONJUVI + R2 (n=273) vs **13.9 months** (95% CI: 11.5, 16.4) with R2 (n=275) (HR‡=0.43 [95% CI: 0.32, 0.58]; *P*<0.0001) **after a median follow-up of 14.1 months**[1]
  - **57% risk reduction in disease progression or death with MONJUVI + R2 vs R2**

- ORR was **84%** (95% CI: 79%, 88%) in the MONJUVI + R2 arm (n=228/273) vs **72%** (95% CI: 67%, 78%) in the R2 arm (n=199/275)[1]

CI=confidence interval; NR=not reached; NE=not evaluable; HR=hazard ratio.

†Kaplan-Meier estimates.[1,3]
‡Hazard ratio based on a stratified Cox proportional hazard model.[1,3]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

Infections

Fatal and serious infections, including opportunistic infections, occurred in patients during treatment with MONJUVI and following the last dose.

Among 274 patients with FL who received MONJUVI in combination with lenalidomide and rituximab in inMIND, Grade 3 or higher infections occurred in 24%, including fatal infections in 1.1% of patients.

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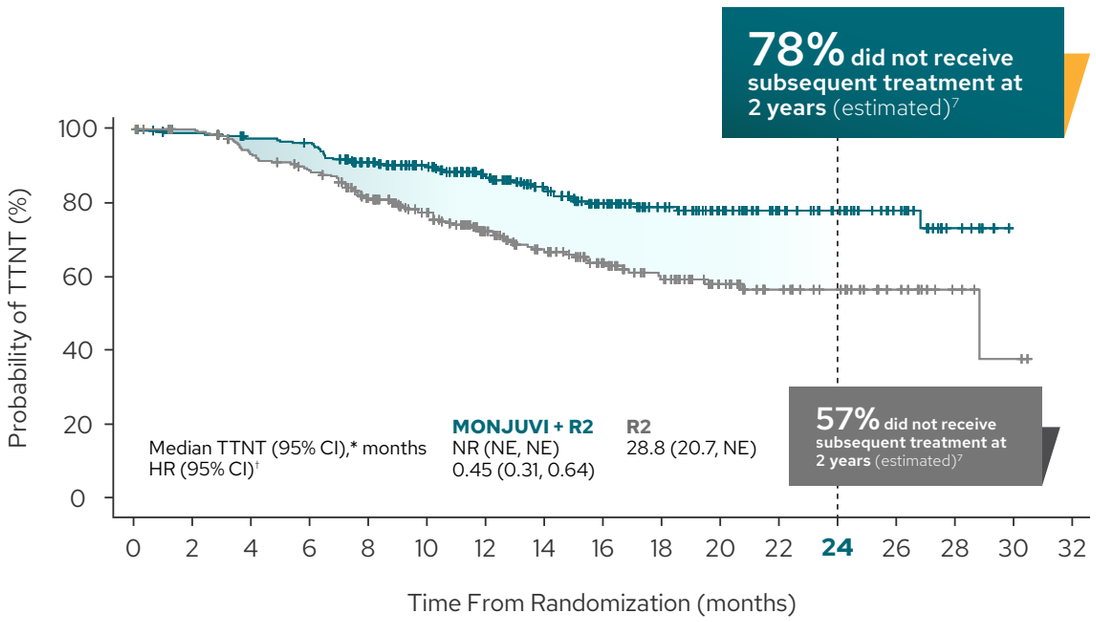
Median time to next treatment not reached with MONJUVI + R2 vs 28.8 months with R2[3,8]

Exploratory Endpoint



Number of patients at risk

MONJUVI + R2	273	268	261	257	224	199	162	132	105	88	67	43	34	22	7	0	0
R2	275	268	248	233	199	166	124	101	78	62	43	30	23	13	5	2	0

Time to next treatment was defined as the time from randomization to start of next anti-lymphoma therapy for any reason or death due to any cause, whichever occurs first.[8]

Limitations of Analysis

The decision to initiate subsequent treatment was made by the treating physician and patient and is subject to variability based on investigator interpretation of patient and disease characteristics. The time to next treatment analysis is exploratory in nature and should be interpreted with caution.

TTNT=time to next treatment.

*Kaplan-Meier estimates.[3]
†Estimated using a stratified Cox proportional hazard model.[3]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

Infections (cont'd)

The most frequent Grade ≥ 3 infections were respiratory tract infections (19%), including Grade 3 or higher pneumonia (14%) and COVID-19 infection (11%). Opportunistic infections of any grade occurred in 6% of patients, including herpes simplex or zoster infection (5%), fungal pneumonia (1.1%, including *Pneumocystis jirovecii* pneumonia in 0.4%), and cytomegalovirus (CMV) reactivation (0.4%).

Monitor patients for signs and symptoms of infection and manage infections as appropriate. Consider infection prophylaxis per institutional guidelines. Consider treatment with subcutaneous or intravenous immunoglobulin (IVIG) as appropriate.

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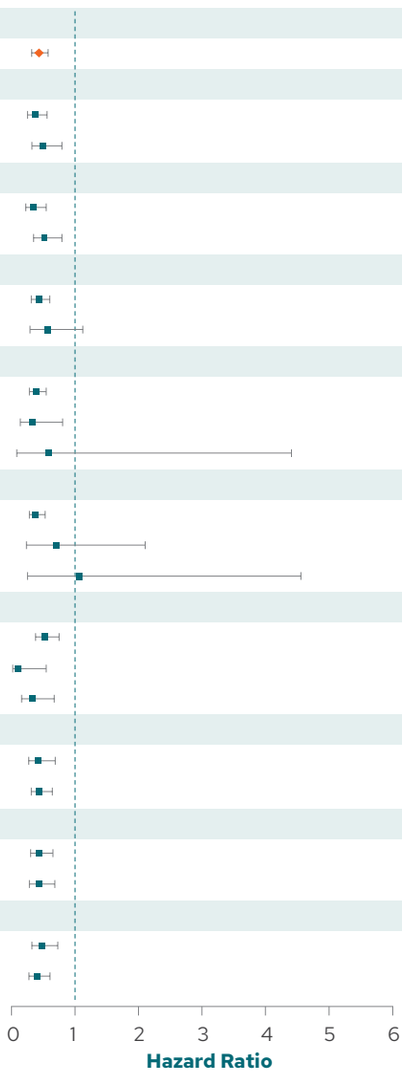
PFS benefit was consistent across patient subgroups with MONJUVI + R2[3]*

	MONJUVI + R2 # Events / # Patients Censored	Placebo + R2 # Events / # Patients Censored	HR (95% CI)
Subgroup			
All patients	75/198	131/144	0.43 (0.32, 0.58)
Sex			
Male	40/110	78/71	0.38 (0.26, 0.56)
Female	35/88	53/73	0.51 (0.33, 0.80)
Age group 1			
<65 years	29/108	69/70	0.35 (0.23, 0.55)
≥65 years	46/90	62/74	0.53 (0.35, 0.80)
Age group 2			
<75 years	55/164	102/119	0.44 (0.31, 0.61)
≥75 years	20/34	29/25	0.58 (0.30, 1.12)
Race			
White	61/158	106/113	0.40 (0.29, 0.55)
Asian	11/29	21/21	0.34 (0.14, 0.81)
Other and missing	3/11	4/10	0.60 (0.08, 4.41)
Ethnicity			
Not Hispanic or Latino	62/166	112/114	0.39 (0.28, 0.53)
Hispanic or Latino	8/23	10/14	0.71 (0.24, 2.10)
Other and missing	5/9	9/16	1.07 (0.25, 4.56)
Geographic region			
Europe	52/124	88/105	0.53 (0.38, 0.76)
North America	8/30	11/13	0.12 (0.02, 0.55)
Rest of the world	15/44	32/26	0.33 (0.16, 0.68)
POD24			
Yes	29/56	52/36	0.43 (0.27, 0.69)
No	46/142	79/108	0.45 (0.31, 0.65)
Refractory to prior anti-CD20 therapy			
Yes	45/73	68/47	0.44 (0.30, 0.65)
No	30/125	63/97	0.44 (0.28, 0.68)
Number of prior lines			
1 line	36/110	61/86	0.48 (0.32, 0.74)
≥2 lines	39/88	70/58	0.41 (0.28, 0.61)



- POD24 was defined as progression of disease within 24 months after initial diagnosis[1]
- Refractoriness to prior anti-CD20 therapy was defined as not achieving a CR or PR to a prior regimen containing anti-CD20 mAb, or disease progression occurring during treatment with, or relapse <6 months after last dose of anti-CD20 mAb[8]

Limitations of analysis

The subgroup analysis is exploratory in nature, and inMIND was not designed or powered to evaluate and compare multiple subgroups. These results should be interpreted with caution.

*Analysis by investigator assessment.[3]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

Embryo-Fetal Toxicity

Based on its mechanism of action, MONJUVI may cause fetal B-cell depletion when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during treatment with MONJUVI and for 3 months after the last dose.

The combination of MONJUVI with lenalidomide and rituximab is contraindicated in pregnant women because lenalidomide can cause birth defects and death of the unborn child. Refer to the lenalidomide prescribing information on use during pregnancy.

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A comparable safety profile with MONJUVI + R2 vs R2 alone with no hospitalization required for administration[1,3]

- MONJUVI should be administered with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions[1]
- A similar rate of adverse events of any grade was reported for MONJUVI + R2 (99%) vs R2 alone (99%)[3]
- A similar rate of Grade 3/4 adverse events was reported for MONJUVI + R2 (71%) vs R2 alone (69%)[3]
- Adverse reactions that occurred more frequently (>5% difference) with MONJUVI + R2 vs R2 alone included COVID-19 infection, pneumonia, diarrhea, pruritus, fatigue, musculoskeletal pain, and mucositis[1]

Adverse reactions (≥10%) in patients with relapsed or refractory FL who received MONJUVI in inMIND[1]*		All Grades (%)		Grade 3 or 4 (%)	
		MONJUVI + R2 (n=274)	R2 (n=272)	MONJUVI + R2 (n=274)	R2 (n=272)
Infections	Respiratory tract infection	56	56	18	9
	COVID-19 infection†	34‡	24‡	10	2.9
	Pneumonia†	18	11§	14	7
	Upper respiratory tract infection†	17	22	1.1	0.4
Gastrointestinal disorders	Diarrhea	38	28	0.7	1.8
	Constipation	29	25	0.7	0
	Nausea	18	14	0.4	0.4
	Abdominal pain	13	18	0	2.2
Skin and subcutaneous tissue disorders	Rash†	37	33	3.6	1.5
	Pruritus	16	10	0.4	0
General disorders	Fatigue†	34	25	2.9	0.7
	Pyrexia	19	16	1.8	2.2
	Mucositis†	17	11	0.4	0
	Edema†	11	17	0.7	1.1
Musculoskeletal and connective tissue disorders	Musculoskeletal pain†	24	16	0.4	0.4
	Muscle contracture†	18	19	0	0
Respiratory, thoracic, and mediastinal disorders	Cough	21	19	0	0
Procedural complications	Infusion-related reaction†	16	16	0.7	0.4
Nervous system disorders	Peripheral neuropathy†	12	11	0	0.4
	Headache	10	7	0.4	0
Metabolism and nutrition disorders	Decreased appetite	10	9	0	0.7

The median number of treatment cycles completed with MONJUVI + R2 was 12 (range: 1-12).[3]

Discontinuation of MONJUVI or placebo due to an adverse reaction: MONJUVI + R2 (11%) vs placebo + R2 (7%).[1,3]

*Table includes a combination of grouped and ungrouped terms. Adverse reactions were graded using NCI CTCAE version 5.0.[1]
†Grouped term. See full Prescribing Information for other related terms.[1]
‡Includes 2 fatal outcomes.[1]
§Includes 3 fatal outcomes, including 2 reported under COVID-19 infection.[1]

IMPORTANT SAFETY INFORMATION

Adverse Reactions

In the MONJUVI arm, serious adverse reactions occurred in 33% of patients, including serious infections in 24% of patients (including pneumonia and COVID-19 infection). Other serious adverse reactions in ≥ 2% of patients included renal insufficiency (3.3%), second primary malignancies (2.9%), and febrile neutropenia (2.6%). Fatal adverse reactions occurred in 1.5% of patients, including from COVID-19, sepsis, and adenocarcinoma.

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Select laboratory abnormalities (>20%) worsening from baseline in patients with relapsed or refractory FL who received MONJUVI in inMIND[1]

Laboratory Abnormality	All Grades (%)*		Grade 3 or 4 (%)*	
	MONJUVI + R2	R2	MONJUVI + R2	R2
Hematology				
Neutrophils decreased	75	71	48	44
Hemoglobin decreased	60	54	9	7
Lymphocytes decreased	57	51	22	19
Platelets decreased	40	43	8	9
Chemistry				
Alanine aminotransferase increased	47	42	1.5	1.5
Alkaline phosphatase increased	33	27	0	0
Creatinine increased	29	30	1.5	0.7
Aspartate aminotransferase increased	29	31	0	0.4
Glucose increased	28	28	0.4	1.1
Potassium decreased	24	24	3.3	3
Sodium decreased	24	22	1.5	0.4

*The denominator used to calculate the rate was 268-274 based on the number of patients with a baseline value and at least 1 post-treatment value.[1]

IMPORTANT SAFETY INFORMATION

Adverse Reactions (cont'd)

Adverse reactions led to permanent discontinuation of MONJUVI in 11% of patients and dosage interruptions in 74%. The most frequent adverse reactions leading to dosage interruptions of MONJUVI were neutropenia (37% of all patients), COVID-19 (22%), pneumonia (11%), and infusion-related reaction (8%).

REFERENCES: 1. MONJUVI Prescribing Information. Wilmington, DE: Incyte Corporation. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V.4.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed May 20, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** Sehn LH, Hübel K, Luminari S, et al. Tafasitamab, lenalidomide, and rituximab in relapsed or refractory follicular lymphoma (inMIND): a global, phase 3, randomised controlled trial. *Lancet*. 2026;407(10524):133-146. doi:10.1016/S0140-6736(25)01778-7 **4.** Link BK, Day B, Zhou X, et al. Second-line and subsequent therapy and outcomes for follicular lymphoma in the United States: data from the observational National LymphoCare study. *Br J Haematol*. 2019;184(4):660-663. doi:10.1111/bjh.15149 **5.** Casulo C, Dixon JG, Le-Rademacher J, et al. Validation of POD24 as a robust early clinical end point of poor survival in FL from 5225 patients on 13 clinical trials. *Blood*. 2022;139(11):1684-1693. doi:10.1182/blood.2020010263 **6.** Solal-Céligny P, Lepage E, Brousse N, et al. Doxorubicin-containing regimen with or without interferon alfa-2b for advanced follicular lymphomas: final analysis of survival and toxicity in the Groupe d'Etude des Lymphomes Folliculaires 86 trial. *J Clin Oncol*. 1998;16(7):2332-2338. doi:10.1200/jco.1998.16.7.2332 **7.** Data on file. Incyte Corporation. **8.** Sehn LH, Hübel K, Luminari S, et al. Tafasitamab, lenalidomide, and rituximab in relapsed or refractory follicular lymphoma (inMIND): a global, phase 3, randomised controlled trial. *Lancet*. 2026;407(10524)(Suppl):133-146. doi:10.1016/S0140-6736(25)01778-7

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Reach for MONJUVI for both early and late relapsing 2L follicular lymphoma patients[1,8]

Significant risk reduction in disease progression or death[1]

- **Consistent PFS benefit across patient subgroups,* including those with early or late relapse[8]**

*PFS subgroup analysis is exploratory in nature and was not tested for statistical significance

In an exploratory analysis, median time to next treatment not reached with MONJUVI + R2 vs 28.8 months with R2[3†]

- **In the MONJUVI + R2 arm, 78% did not receive subsequent treatment** at 2 years after randomization (estimated)[7]
- Time to next treatment analysis was not tested for statistical significance[3]

MONJUVI + R2 is a fixed duration treatment that can be administered in an outpatient setting without hospitalization required[1]

A comparable safety profile with MONJUVI + R2 vs R2 alone[1,3]

- Adverse reactions that occurred more frequently (>5% difference) with MONJUVI + R2 vs R2 alone included COVID-19 infection, pneumonia, diarrhea, pruritus, fatigue, musculoskeletal pain, and mucositis[1]
- Serious adverse reactions occurred in 33% of patients who received MONJUVI + R2, including serious infections in 24% of patients (including pneumonia and COVID-19 infection). Other serious adverse reactions in ≥2% of patients included renal insufficiency (3.3%), second primary malignancies (2.9%), and febrile neutropenia (2.6%)[1]

*Time to next treatment was defined as the time from randomization to start of next anti-lymphoma therapy for any reason or death due to any cause, whichever occurs first.[8]

NCCN CATEGORY 1

NCCN recommends as an NCCN Category 1 Preferred Treatment Option

NCCN Guidelines® **recommend tafasitamab-cxix (MONJUVI) in combination with rituximab and lenalidomide as a Category 1 preferred second-line** or subsequent therapy option (if not previously used) for FL after ≥1 prior systemic therapy, including an anti-CD20 mAb.[2]

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For information about patient assistance, please visit HCP.IncyteCARES.com/MONJUVI.

IMPORTANT SAFETY INFORMATION

Adverse Reactions (cont'd)

The most common adverse reactions (≥ 20%) in people receiving MONJUVI were respiratory tract infections (56%) (including COVID-19 infection and pneumonia), diarrhea (38%), rash (37%), fatigue (34%), constipation (29%), musculoskeletal pain (24%), and cough (21%). The most common Grade 3 or 4 laboratory abnormalities (≥ 20%) were decreased neutrophils (48%) and decreased lymphocytes (22%).

Warnings and Precautions

Infusion-Related Reactions

MONJUVI (tafasitamab-cxix) can cause infusion-related reactions (IRRs).

In inMIND, infusion-related reactions occurred in 16% of the 274 patients with FL who received MONJUVI in combination with lenalidomide and rituximab. Signs and symptoms included fever, chills, rash, flushing, dyspnea, and hypertension. These reactions were generally managed with temporary interruption of the infusion and/or with supportive medication.

Premedicate patients prior to starting MONJUVI infusion. Monitor patients frequently during infusion. Based on the severity of the infusion-related reaction, interrupt or discontinue MONJUVI. Institute appropriate medical management.

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