

# MONJUVI

tafasitamab-cxix

rituximab &  
lenalidomide

inMIND Clinical Data

## MONJUVI + R2—the first and only CD19- and CD20-targeted immunotherapy combination approved for **2L+ follicular lymphoma** patients<sup>1</sup>

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

R2=rituximab and lenalidomide; 2L+=second-line plus; mAb=monoclonal antibody.

**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.**<sup>2</sup>

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### 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).

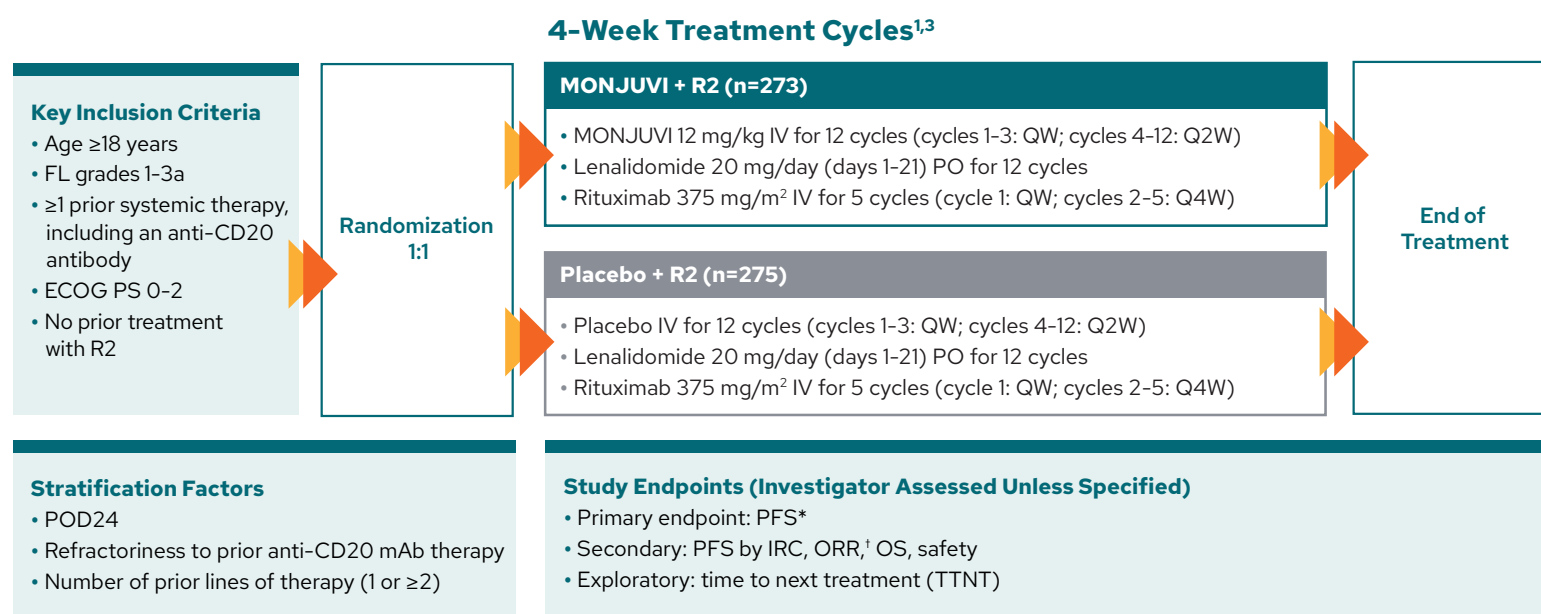
In inMIND, infusion-related reactions occurred in 16% of the 274 patients with FL who received MONJUVI in combination with lenalidomide and rituximab. Signs and symptoms included fever, chills, rash, flushing, dyspnea, and hypertension. These reactions were generally managed with temporary interruption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

# inMIND: 548 patients with FL were randomized to receive MONJUVI + R2 or placebo + R2 in a Phase 3, double-blind, international, multicenter study<sup>1,3</sup>



**MONJUVI + R2 was administered as a fixed duration treatment of 12 cycles.<sup>1‡</sup>**

FL=follicular lymphoma; ECOG PS=Eastern Cooperative Oncology Group performance status; IV=intravenous; QW=once weekly; Q2W=once every 2 weeks; PO=by mouth; Q4W=once every 4 weeks; POD24=progression of disease within 24 months after initial diagnosis; PFS=progression-free survival; IRC=Independent Review Committee; ORR=overall response rate; OS=overall survival.

\*PFS was defined as the time from randomization to first documented disease progression per Lugano 2014 criteria, or death from any cause, whichever occurs first.<sup>4</sup>

<sup>†</sup>Complete response plus partial response.

<sup>‡</sup>Patients received study treatment for up to 12 cycles in the absence of disease progression or unacceptable toxicity.<sup>4</sup>

## 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.

**Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).**

# MONJUVI + R2 was studied in a 2L+ FL broad patient population that included tough-to-treat patients as well as those that relapsed later in their disease<sup>1,5-7</sup>

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

## Baseline Patient Characteristics<sup>3,8</sup>

| Select Baseline Characteristic                  | MONJUVI + R2<br>(n=273) | Placebo + R2<br>(n=275) |
|-------------------------------------------------|-------------------------|-------------------------|
| Median age, years (range)                       | 64 (36, 88)             | 64 (31, 85)             |
| Sex, %                                          | Male                    | 55                      |
|                                                 | Female                  | 45                      |
| Race, %*                                        | White                   | 80                      |
|                                                 | Asian                   | 15                      |
|                                                 | Other races             | 1                       |
| FL grade at trial entry, % <sup>†</sup>         | Grade 1                 | 22                      |
|                                                 | Grade 2                 | 52                      |
|                                                 | Grade 3a                | 25                      |
| 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<sup>4</sup>
- POD24 was defined as progression of disease within 24 months after initial diagnosis<sup>1</sup>

GELF=Groupe d'Etude des Lymphomes Folliculaires; 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.<sup>3</sup>

<sup>†</sup>FL grade at trial entry was not reported for 3 patients in the MONJUVI + R2 arm and 1 patient in the placebo + R2 arm.<sup>8</sup>

## IMPORTANT SAFETY INFORMATION

### Warnings and Precautions (cont'd)

#### Infections

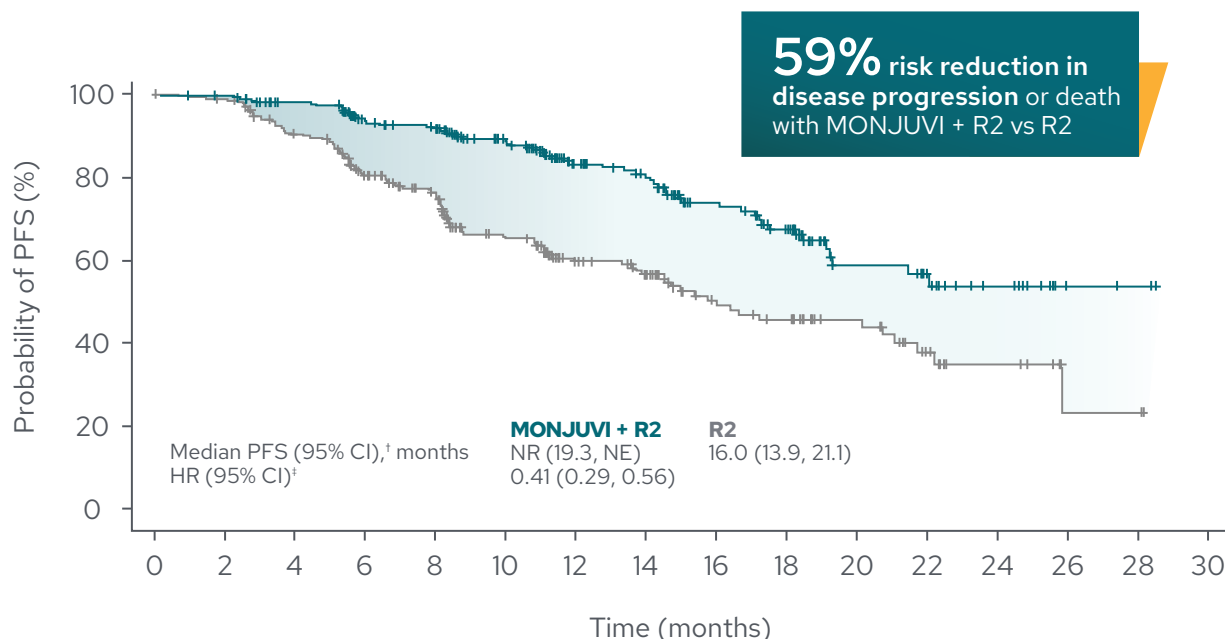
Fatal and serious infections, including opportunistic infections, occurred in patients during treatment with MONJUVI and following the last dose.

**Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).**

# 59% risk reduction in disease progression or death with MONJUVI + R2 as assessed by IRC<sup>3</sup>

## IRC-Assessed PFS (Secondary Endpoint)

Median PFS was not reached with MONJUVI + R2 vs 16 months with R2<sup>3\*</sup>



Number of patients at risk

|                     |     |     |     |     |     |     |     |    |    |    |    |    |    |   |   |   |
|---------------------|-----|-----|-----|-----|-----|-----|-----|----|----|----|----|----|----|---|---|---|
| <b>MONJUVI + R2</b> | 273 | 260 | 246 | 210 | 200 | 162 | 113 | 98 | 72 | 58 | 28 | 20 | 12 | 3 | 2 | 0 |
| <b>R2</b>           | 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<sup>†</sup> 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<sup>‡</sup>=0.43 [95% CI: 0.32, 0.58];  $P<0.0001$ ) **after a median follow-up of 14.1 months<sup>1</sup>**

– **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)<sup>1</sup>

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

<sup>†</sup>Kaplan-Meier estimates.<sup>1,3</sup>

<sup>‡</sup>Hazard ratio based on a stratified Cox proportional hazard model.<sup>1,3</sup>

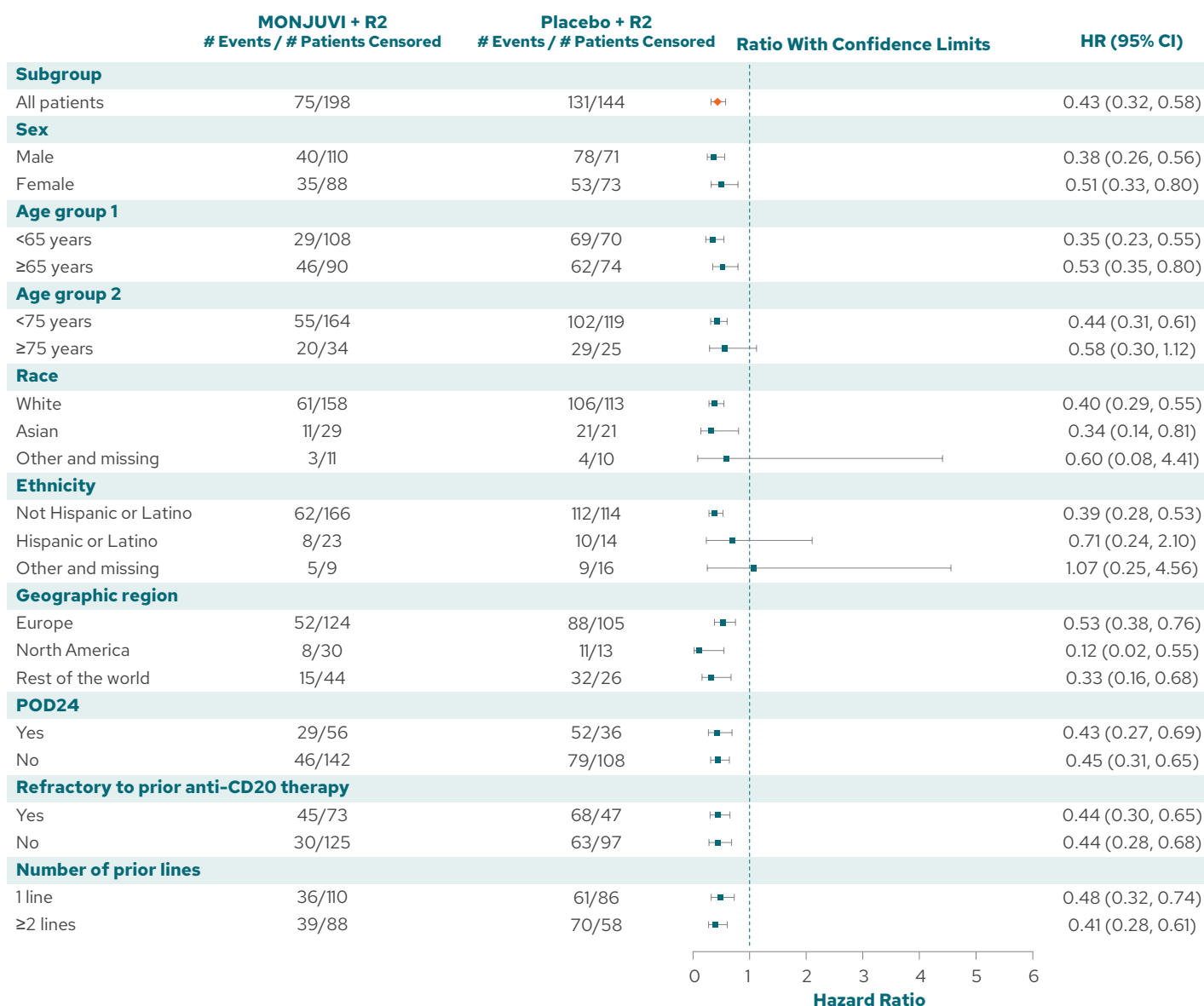
## IMPORTANT SAFETY INFORMATION Warnings and Precautions (cont'd)

### Infections (cont'd)

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. The most frequent Grade  $\geq 3$  infections were respiratory tract infections (19%), including Grade 3 or higher pneumonia (14%) and COVID-19 infection (11%).

Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).

# PFS benefit was consistent across patient subgroups with MONJUVI + R2<sup>3\*</sup>



- POD24 was defined as progression of disease within 24 months after initial diagnosis<sup>1</sup>
- 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<sup>4</sup>

## 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.<sup>4</sup>

## IMPORTANT SAFETY INFORMATION

### Warnings and Precautions (cont'd)

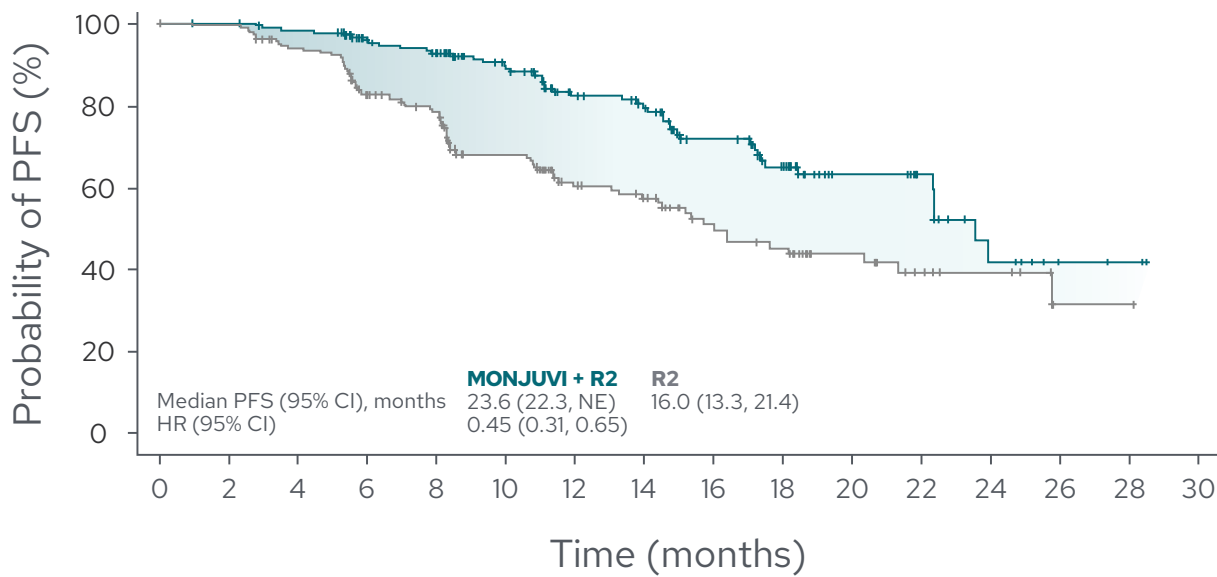
#### Infections (cont'd)

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%).

Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).

# Non-POD24 (late relapse): Consistent PFS benefit regardless of time to relapse<sup>4\*</sup>

## Non-POD24 (late relapse)



Number of patients at risk

|              |     |     |     |     |     |     |    |    |    |    |    |    |   |   |   |   |
|--------------|-----|-----|-----|-----|-----|-----|----|----|----|----|----|----|---|---|---|---|
| MONJUVI + R2 | 188 | 180 | 175 | 152 | 143 | 118 | 87 | 78 | 58 | 45 | 24 | 17 | 8 | 3 | 2 | 0 |
| R2           | 187 | 182 | 168 | 140 | 127 | 91  | 61 | 54 | 36 | 31 | 21 | 14 | 9 | 2 | 2 | 0 |

### Limitations of Analysis

The POD24 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.<sup>4</sup>

### IMPORTANT SAFETY INFORMATION Warnings and Precautions (cont'd)

#### Infections (cont'd)

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.

#### Embryo-Fetal Toxicity

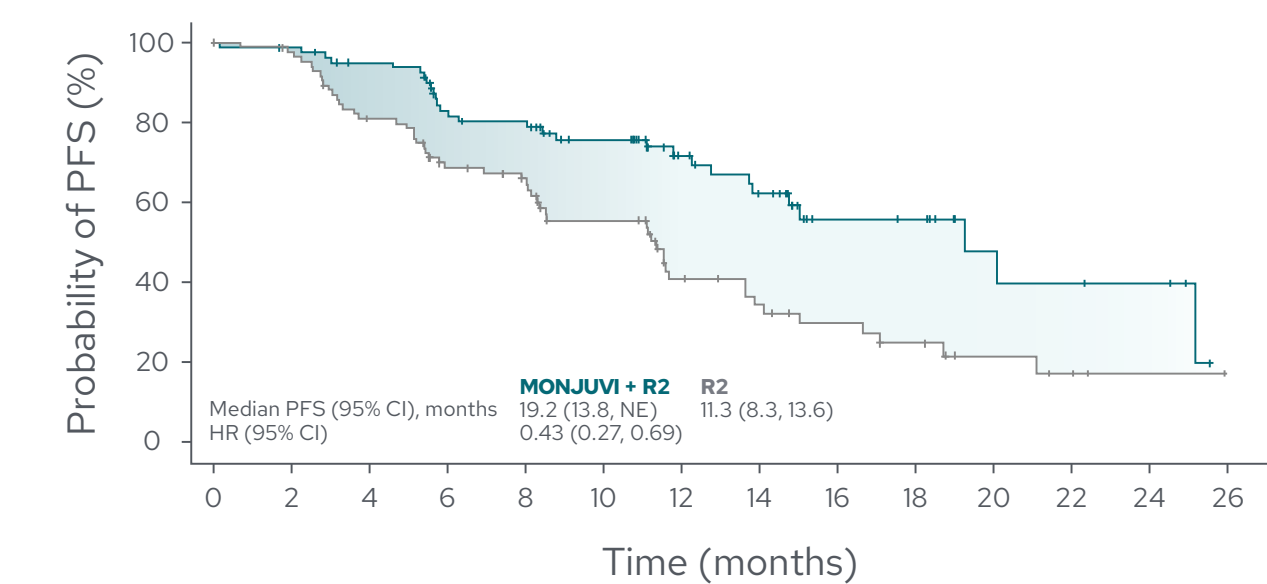
Based on its mechanism of action, MONJUVI may cause fetal B-cell depletion when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during treatment with MONJUVI and for 3 months after the last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

Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).

# POD24 (early relapse): Consistent PFS benefit regardless of time to relapse<sup>4\*</sup>

## POD24 (early relapse)



Number of patients at risk

|              |    |    |    |    |    |    |    |    |    |    |   |   |   |   |
|--------------|----|----|----|----|----|----|----|----|----|----|---|---|---|---|
| MONJUVI + R2 | 85 | 81 | 75 | 60 | 57 | 46 | 32 | 25 | 13 | 12 | 6 | 5 | 4 | 0 |
| R2           | 88 | 83 | 67 | 52 | 46 | 35 | 21 | 16 | 12 | 9  | 5 | 2 | 1 | 0 |

POD24 was defined as progression of disease within 24 months after initial diagnosis.<sup>1</sup>

### Limitations of Analysis

The POD24 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.

<sup>4</sup>Analysis by investigator assessment.<sup>4</sup>

### IMPORTANT SAFETY INFORMATION

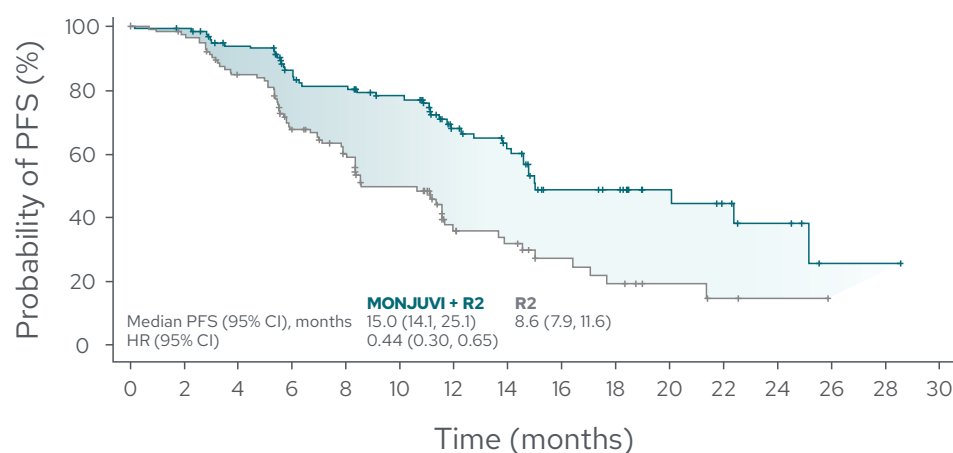
#### Adverse Reactions

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).

Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).

# PFS benefit was consistent regardless of anti-CD20 refractory status with MONJUVI + R2<sup>4\*</sup>

## Anti-CD20 Refractory



Number of patients at risk

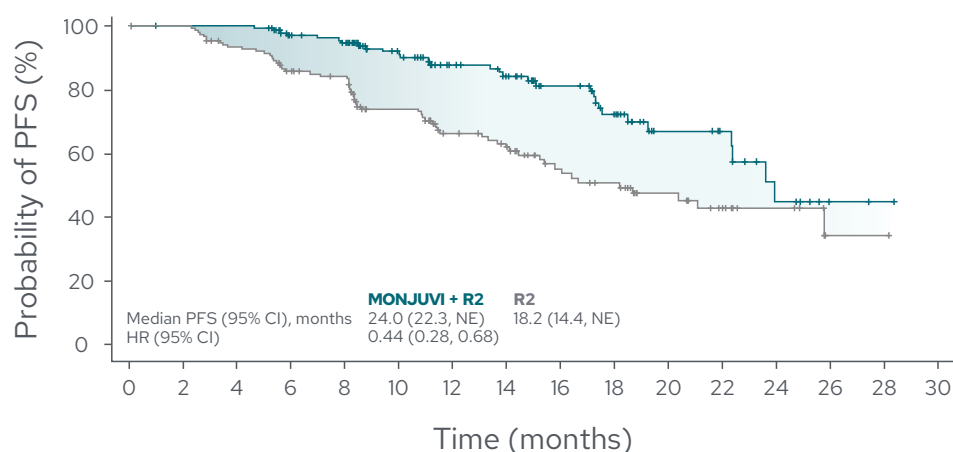
|                     |     |     |     |    |    |    |    |    |    |    |    |   |   |   |   |   |
|---------------------|-----|-----|-----|----|----|----|----|----|----|----|----|---|---|---|---|---|
| <b>MONJUVI + R2</b> | 118 | 113 | 102 | 86 | 80 | 71 | 46 | 38 | 21 | 19 | 11 | 8 | 5 | 1 | 1 | 0 |
| <b>R2</b>           | 115 | 108 | 91  | 66 | 54 | 41 | 20 | 16 | 10 | 7  | 4  | 2 | 1 | 0 | 0 | 0 |

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.<sup>4</sup>

### Limitations of Analysis

The anti-CD20 refractory status 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.

## Non-anti-CD20 Refractory



Number of patients at risk

|                     |     |     |     |     |     |    |    |    |    |    |    |    |   |   |   |   |
|---------------------|-----|-----|-----|-----|-----|----|----|----|----|----|----|----|---|---|---|---|
| <b>MONJUVI + R2</b> | 155 | 148 | 148 | 126 | 120 | 93 | 73 | 65 | 50 | 38 | 19 | 14 | 7 | 2 | 1 | 0 |
| <b>R2</b>           | 160 | 157 | 144 | 126 | 119 | 85 | 62 | 54 | 38 | 33 | 22 | 14 | 9 | 2 | 2 | 0 |

\*Analysis by investigator assessment.<sup>4</sup>

## IMPORTANT SAFETY INFORMATION

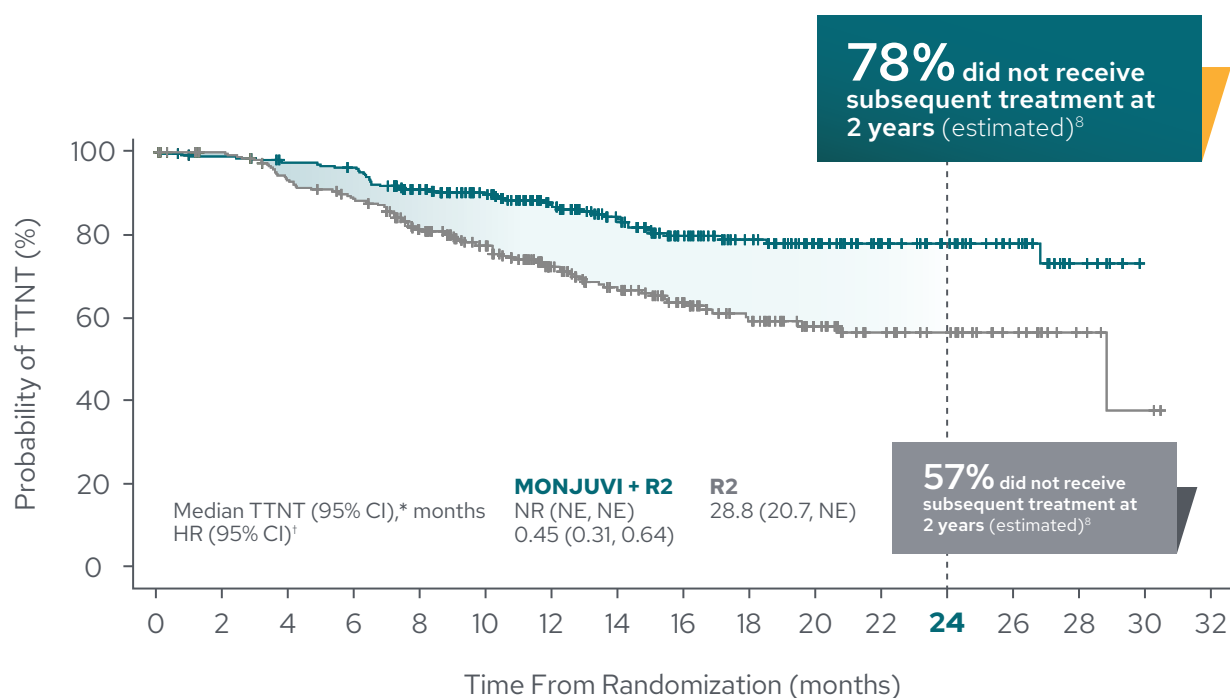
### Adverse Reactions (cont'd)

Other serious adverse reactions in  $\geq 2\%$  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.

Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).

# Median time to next treatment not reached with MONJUVI + R2 vs 28.8 months with R2<sup>3,4</sup>

## Exploratory Endpoint



Number of patients at risk

|                     |     |     |     |     |     |     |     |     |     |    |    |    |    |    |   |   |   |
|---------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|----|----|----|----|----|---|---|---|
| <b>MONJUVI + R2</b> | 273 | 268 | 261 | 257 | 224 | 199 | 162 | 132 | 105 | 88 | 67 | 43 | 34 | 22 | 7 | 0 | 0 |
| <b>R2</b>           | 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.<sup>4</sup>

## 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.

\*Kaplan-Meier estimates.<sup>3</sup>

<sup>†</sup>Estimated using a stratified Cox proportional hazard model.<sup>3</sup>

## 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%).

Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).

# Transformation to DLBCL occurred in 0 patients with MONJUVI + R2 and 9 patients with R2<sup>9\*</sup>

## Exploratory Endpoint

|                                                      | MONJUVI + R2<br>(n=273) | R2<br>(n=275)  |
|------------------------------------------------------|-------------------------|----------------|
| Transformation into more aggressive histology, n (%) | 0 (0.0)                 | 9 (3.3)        |
| Rate of transformation, % (95% CI)                   | 0 (0.0, 1.3)            | 3.3 (1.5, 6.1) |

Transformation of FL into a more aggressive histology (eg, DLBCL) was defined as the appearance of diffuse areas of large-cell lymphoma cells within a lymphoma site as proven by a histological examination of a tumor biopsy at the time of disease progression.<sup>9</sup>

## Limitations of Analysis

The histological transformation analysis is exploratory in nature and should be interpreted with caution.

DLBCL=diffuse large B-cell lymphoma.

\*Data was assessed at the time of the primary analysis.

## IMPORTANT SAFETY INFORMATION

### Adverse Reactions (cont'd)

The most common adverse reactions ( $\geq 20\%$ ) 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 ( $\geq 20\%$ ) were decreased neutrophils (48%) and decreased lymphocytes (22%).

Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).

# A comparable safety profile with MONJUVI + R2 vs R2 alone with no hospitalization required for administration<sup>1,3</sup>

- MONJUVI should be administered with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions<sup>1</sup>
- A similar rate of adverse events of any grade was reported for MONJUVI + R2 (99%) vs R2 alone (99%)<sup>3</sup>
- A similar rate of Grade 3/4 adverse events was reported for MONJUVI + R2 (71%) vs R2 alone (69%)<sup>3</sup>
- 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<sup>1</sup>

| Adverse reactions (≥10%) in patients with relapsed or refractory FL who received MONJUVI in inMIND <sup>1*</sup> |                                                | 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 <sup>†</sup>                | 34 <sup>‡</sup>      | 24 <sup>‡</sup> | 10                   | 2.9        |
|                                                                                                                  | Pneumonia <sup>†</sup>                         | 18                   | 11 <sup>§</sup> | 14                   | 7          |
|                                                                                                                  | Upper respiratory tract infection <sup>†</sup> | 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 <sup>†</sup>                              | 37                   | 33              | 3.6                  | 1.5        |
|                                                                                                                  | Pruritus                                       | 16                   | 10              | 0.4                  | 0          |
| General disorders                                                                                                | Fatigue <sup>†</sup>                           | 34                   | 25              | 2.9                  | 0.7        |
|                                                                                                                  | Pyrexia                                        | 19                   | 16              | 1.8                  | 2.2        |
|                                                                                                                  | Mucositis <sup>†</sup>                         | 17                   | 11              | 0.4                  | 0          |
|                                                                                                                  | Edema <sup>†</sup>                             | 11                   | 17              | 0.7                  | 1.1        |
| Musculoskeletal and connective tissue disorders                                                                  | Musculoskeletal pain <sup>†</sup>              | 24                   | 16              | 0.4                  | 0.4        |
|                                                                                                                  | Muscle contracture <sup>†</sup>                | 18                   | 19              | 0                    | 0          |
| Respiratory, thoracic, and mediastinal disorders                                                                 | Cough                                          | 21                   | 19              | 0                    | 0          |
| Procedural complications                                                                                         | Infusion-related reaction <sup>†</sup>         | 16                   | 16              | 0.7                  | 0.4        |
| Nervous system disorders                                                                                         | Peripheral neuropathy <sup>†</sup>             | 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).<sup>3</sup>



Discontinuation of MONJUVI or placebo due to an adverse reaction: MONJUVI + R2 (11%) vs placebo + R2 (7%).<sup>1,3</sup>

\*Table includes a combination of grouped and ungrouped terms. Adverse reactions were graded using NCI CTCAE version 5.0.<sup>1</sup>

<sup>†</sup>Grouped term. See full Prescribing Information for other related terms.<sup>1</sup>

<sup>‡</sup>Includes 2 fatal outcomes.<sup>1</sup>

<sup>§</sup>Includes 3 fatal outcomes, including 2 reported under COVID-19 infection.<sup>1</sup>

Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).

# Select laboratory abnormalities (>20%) worsening from baseline in patients with relapsed or refractory FL who received MONJUVI in inMIND<sup>1</sup>

| Laboratory Abnormality               | All Grades (%)* |    | Grade 3 or 4 (%)* |     |
|--------------------------------------|-----------------|----|-------------------|-----|
|                                      | MONJUVI + R2    | R2 | MONJUVI + R2      | R2  |
| <b>Hematology</b>                    |                 |    |                   |     |
| Neutrophils decreased                | 75              | 71 | 48                | 44  |
| Hemoglobin decreased                 | 60              | 54 | 9                 | 7   |
| Lymphocytes decreased                | 57              | 51 | 22                | 19  |
| Platelets decreased                  | 40              | 43 | 8                 | 9   |
| <b>Chemistry</b>                     |                 |    |                   |     |
| 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.<sup>1</sup>

## IMPORTANT SAFETY INFORMATION

### Warnings and Precautions

#### Infusion-Related Reactions

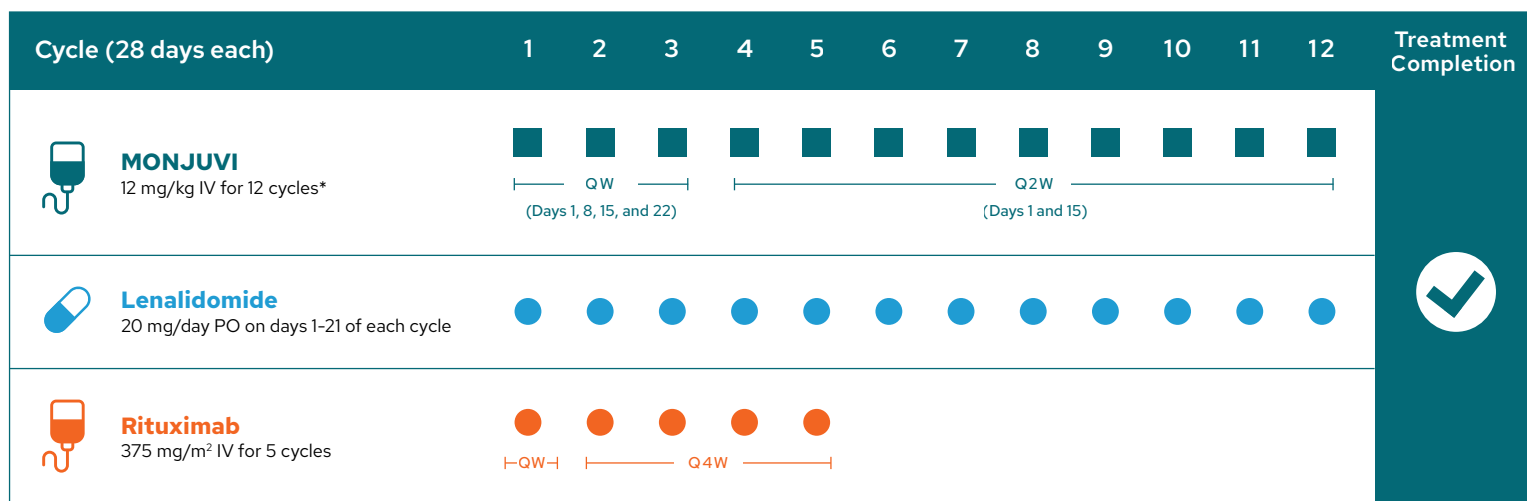
MONJUVI can cause infusion-related reactions (IRRs).

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.

Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).

# MONJUVI + R2 is a fixed duration treatment<sup>1</sup>

## Dosing and Administration<sup>1</sup>



Refer to the rituximab Prescribing Information and the lenalidomide Prescribing Information for the respective dosage recommendations, including lenalidomide dosage recommendations for patients with renal insufficiency.



**MONJUVI is a 12-cycle fixed duration treatment.<sup>1</sup>**



**MONJUVI + R2 can be administered in a local outpatient setting without hospitalization required.<sup>1</sup>**

Administer premedications 30 minutes to 2 hours prior to starting MONJUVI infusion to minimize infusion-related reactions (IRRs). Premedications may include acetaminophen, histamine H<sub>1</sub> receptor antagonists, histamine H<sub>2</sub> receptor antagonists, and/or glucocorticosteroids.<sup>1</sup>

For patients not experiencing IRRs during the first 3 infusions, premedication is optional for subsequent infusions. If a patient experiences an IRR, administer premedications before each subsequent infusion.<sup>1</sup>

Refer to the lenalidomide Prescribing Information for recommendations on prophylaxis for venous and arterial thrombotic events.

MONJUVI should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage IRRs.<sup>1</sup> For details on dose modifications and management of adverse reactions for IRRs and myelosuppression, please refer to the full Prescribing Information.

\*Recommended dose of MONJUVI is based on the patient's actual body weight.<sup>1</sup>

**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 21, 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.** 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 **5.** 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 **6.** 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 **7.** 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 **8.** Data on file. Incyte Corporation. **9.** Sehn LH, Hübel K, Luminari S, et al. Outcomes from the phase 3 inMIND study of tafasitamab plus lenalidomide and rituximab for patients with relapsed/refractory follicular lymphoma. Presented at: 18th International Conference on Malignant Lymphoma (ICML); June 17-21, 2025; Lugano, Switzerland.

Please see additional Important Safety Information throughout and the Full [Prescribing Information](#).

# Reach for MONJUVI for both early and late relapsing 2L follicular lymphoma patients<sup>1,4</sup>



## Significant risk reduction in disease progression or death<sup>1</sup>

- **Consistent PFS benefit across patient subgroups,\* including those with early or late relapse<sup>4</sup>**

\*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<sup>3†</sup>

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



## MONJUVI + R2 is a fixed duration treatment that can be administered in an outpatient setting without hospitalization required<sup>1</sup>



## A comparable safety profile with MONJUVI + R2 vs R2 alone<sup>1,3</sup>

- 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<sup>1</sup>
- 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 malignancy (2.9%), and febrile neutropenia (2.6%)<sup>1</sup>

<sup>†</sup>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.<sup>4</sup>



## NCCN recommends as an NCCN Category 1 Preferred Treatment Option

NCCN Guidelines<sup>®</sup> 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.<sup>2</sup>

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For information about patient assistance, please visit [HCP.IncyteCARES.com/MONJUVI](https://HCP.IncyteCARES.com/MONJUVI)

## IMPORTANT SAFETY INFORMATION Warnings and Precautions (cont'd)

### Infusion-Related Reactions

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](#).



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