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tafasitamab

# Tafasitamab (MINJUVI) + Lenalidomide

*„5-year Follow-up of the L-MIND trial“*[1]

and *„Tafasitamab for the Treatment of R/R DLBCL in the US and EU Real-World Setting”*[2-4]

MINJUVI is indicated in combination with lenalidomide followed by MINJUVI monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after at least one line of systemic CD20-targeted antibody therapy who are not eligible for autologous stem cell transplantation (ASCT).[5]

**1** Duell J et al., Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480 **2** Kim Saverno et al., Tafasitamab for the Treatment of Relapsed or Refractory Diffuse Large B-Cell Lymphoma in the US Real-World Setting; Oral presentation 265 at ASH Dec 2023; https://www.incytemi.com/document/Poster/ASH%202023%20-%20Tafasitamab%20RWE%20(oral%20presentation).pdf **3** Herbaux et al, Poster 1214; EarlyMIND, a Retrospective Multicenter Study in Real-World Settings to Characterize Tafasitamab-Lenalidomide Efficacy in Transplant-Ineligible Patients With Relapsed/Refractory Large B-Cell Lymphoma; presented during EHA 2024, June 2024 **4** Gutiérrez et al, Poster 1203; Tafasitamab plus lenalidomide as salvage therapy in DLBCL: the Spanish Group of Lymphoma (GELTAMO) real-world experience; presented during EHA 2024, June 2024
**5** MINJUVI Professional Information. see www.swissmedicinfo.ch

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# L-MIND: Study design[1,2]

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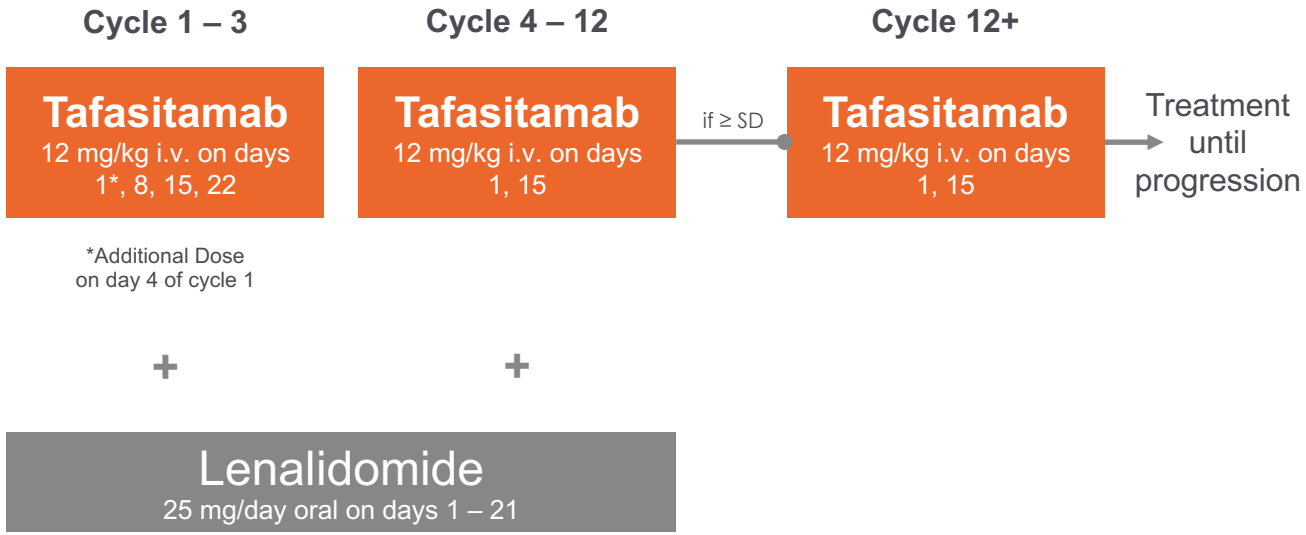
## Open-label, multicentric, single-arm Phase II study (n = 81)

**Inclusion criteria:**

- R/R DLBCL
- Ineligible for ASCT
- Refused ASCT
- 1–3 prior therapies
- ECOG PS 0 – 2

**Exclusion criteria:**

- CNS involvement
- Prior CD19 therapy
- Prior iMID therapy




**Primary endpoint:**

- Objective response rate (ORR)

**Selected secondary endpoints:**

- Duration of response (DoR),
- Overall survival (OS),
- Progression free survival (PFS)
- Safety

**ASCT:** autologous stem cell transplantation **ECOG PS:** Eastern Cooperative Oncology Group Performance Status **R/R DLBCL:** relapsed or refractory diffuse large B-cell lymphoma
**SD:** stable disease **iMID:** immunemodulatory imide drug


**1** MINJUVI Professional Information. see www.swissmedicinfo.ch
**2** Salles G et al., Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study., Lancet Oncol. 2020; 21(7) 978-88.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# L-MIND: Patient characteristics[1,2,3]

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**Selected patient characteristics**

| | | |
|---|---|---|
| Median age[1] | Median | 72 years (Range 41 – 86) |
| Sex[1] | Male | 54 % |
| | Female | 46 % |
| ECOG PS[1] | 0 – 1 | 91 % |
| Risk (IPI)[3] | 0 – 2 | 50 % |
| | 3 – 5 | 50 % |
| Ann Arbor Stage[2] | I – II | 25 % |
| | III – IV | 75 % |
| Elevated LDH[3] | Yes | 55 % |
| Cell of origin (IHC)[3] | GCB | 48 % |
| | Non-GCB | 28 % |
| | Unknown | 25 % |

**Selected prior therapies**

| | | |
|---|---|---|
| Number of prior therapies[1] | 1 | 49 % |
| Median: 2 | 2 | 43 % |
| | 3 | 6 % |
| Primary refractory (%)[1] | Yes | 19 % |
| Refractory to last therapy (%)[1] | Yes | 44 % |
| Refractory to Rituximab (%)[1] | Yes | 42 % |
| Prior ASCT (%)[1] | Yes | 11 % |
| Prior CD20-containing regimen (%)[1] | Yes | 100 % |

**GCB:** germinal center B **IHC:** immunohistochemistry **IPI:** international prognosis index **LDH:** lactate dehydrogenase **ECOG PS:** Eastern Cooperative Oncology Group Performance Status

**1** MINJUVI Professional Information. see www.swissmedicinfo.ch **2** Salles G et al., Tafasitamab plus Lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study, Lancet Oncol. 2020; 21(7) 978-88. **3** Duell J et al., Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480

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# 5-year Data: Best Response[1]

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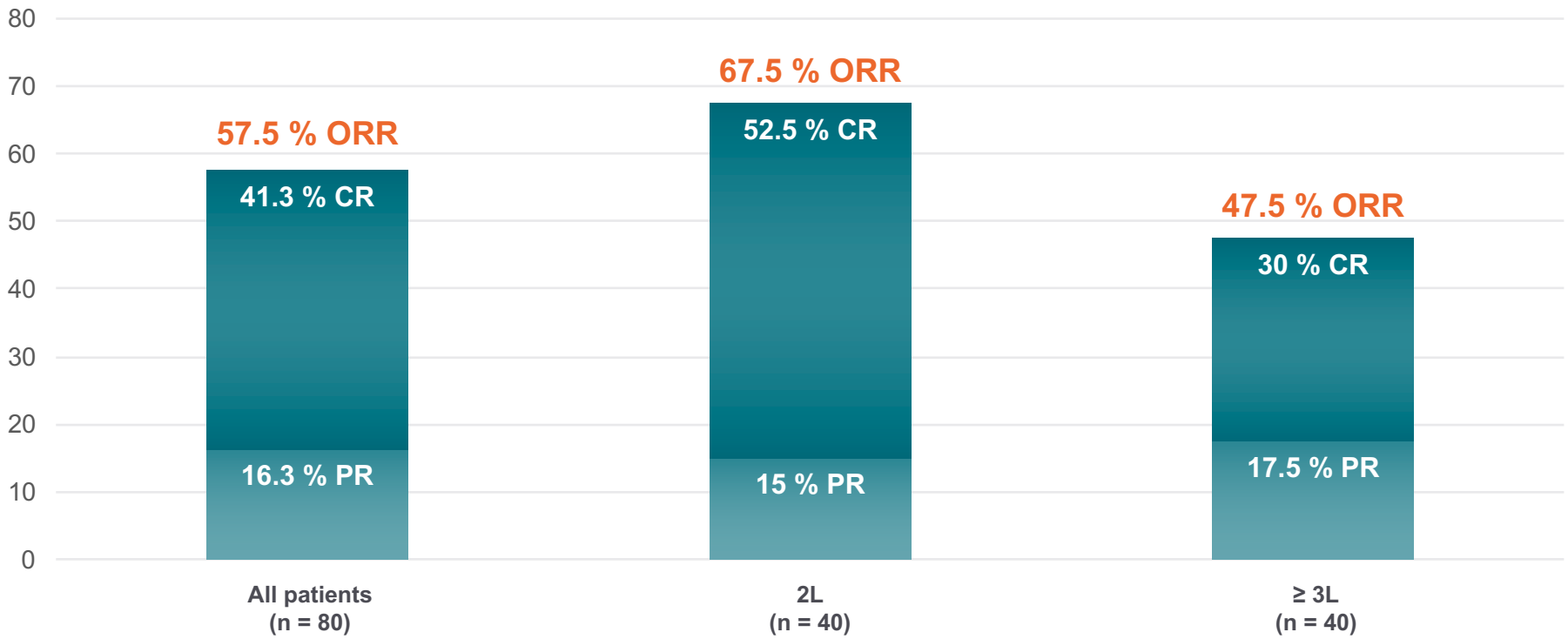
**L-MIND: Objective response rates** (ORR; All patients plus subgroup analyses)[a-c]




Median time to response:
**2.1 Months (1.7 – 34.7)[2]**

**a** Best objective response rate assessed by an independent review committee.
**b** Median follow-up 44 months, data cut-off November 2022.
**c** n = 80 is from the full analysis set from Duell J et al. One patient was not included as he/she only received tafasitamab monotherapy[1,2] The MINJUVI Professional Information refers to an intention-to-treat cohort of n = 81 with 56.8% ORR (39.5% CR and 17.3% PR).

**CR:** complete remission **PR:** partial remission **ORR:** objective response rate **2L:** second line **3L:** third line

**1** Duell J et al., Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480 **2** Duell J et al., Long-term outcomes from the phase II L-MIND study of tafasitamab (MOR208) plus lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma. Haematologica. 2021; 106(9): 2417 – 26.

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# 5-year Data: Efficacy Results - DoR

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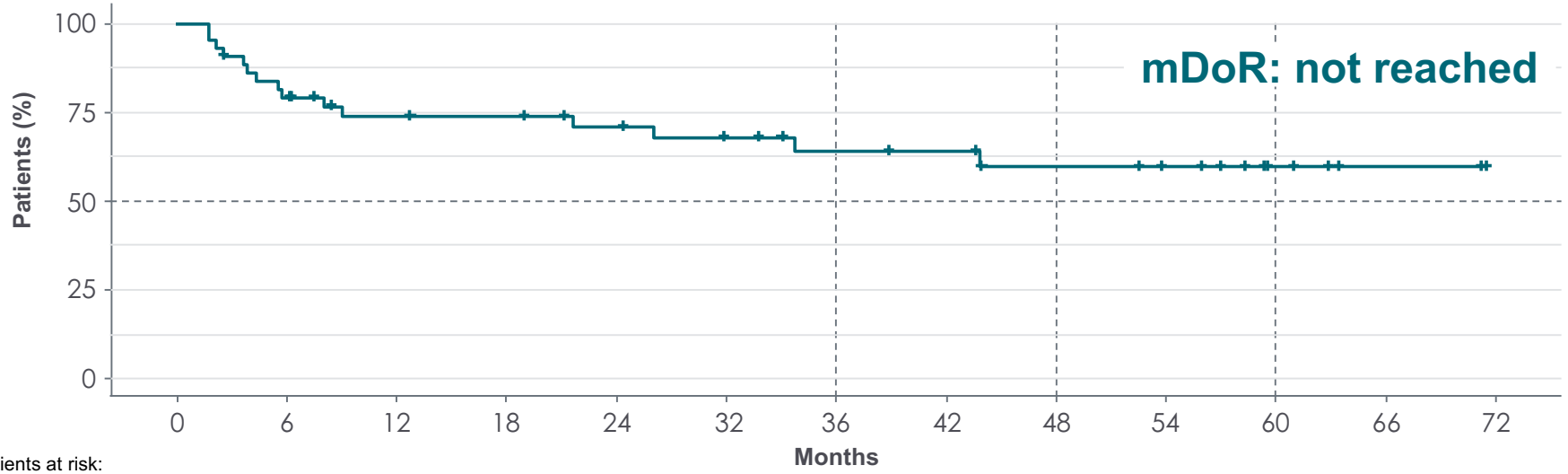
**L-MIND: Median duration of response (DoR)** in patients with PR/CR and after best response[1,a,b]

| Analysis | 3-year [2] 30 Oct 2020 | 5-year final: 14 Nov 2022 | | |
|---|---|---|---|---|
| | | Overall | 2L | ≥3L |
| **mDoR**, months [95% CI] | 43.9 [26.1, NR] | **NR** [33.8, NR] | **NR** [9.1, NR] | **NR** [26.1, NR] |




Patients at risk:

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Overall** | 46 | 34 | 28 | 27 | 24 | 21 | 17 | 16 | 13 | 11 | 5 | 2 | 0 |
| **2L** | 27 | 20 | 16 | 16 | 14 | 12 | 11 | 11 | 10 | 8 | 3 | 2 | 0 |
| **≥3L** | 19 | 14 | 12 | 11 | 10 | 9 | 6 | 5 | 3 | 3 | 2 | 0 | 0 |

**mFU, months [95% CI]**
**Overall 44.0** [29.9, 57.0]

**a** Median overall follow up 44 months data cut-off November 2022.
**b** n = 80 is from the full analysis set from Duell J et al, 2021. One patient was not included as he/she only received tafasitamab monotherapy.[1,2] The MINJUVI Professional Information refers to an intention-to-treat cohort of n = 81.

**CI:** confidence interval **CR:** complete remission **mDoR:** median duration of response **mFU:** median follow-up **NR:** not reached **PR:** partial remission **2L:** second line **3L:** third line

**1** Duell J et al.,Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480 **2** Duell J et al., Long-term outcomes from the phase II L-MIND study of tafasitamab (MOR208) plus lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma. Haematologica. 2021; 106(9): 2417 – 26.

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# 5-year Data: Efficacy Results - DoCR

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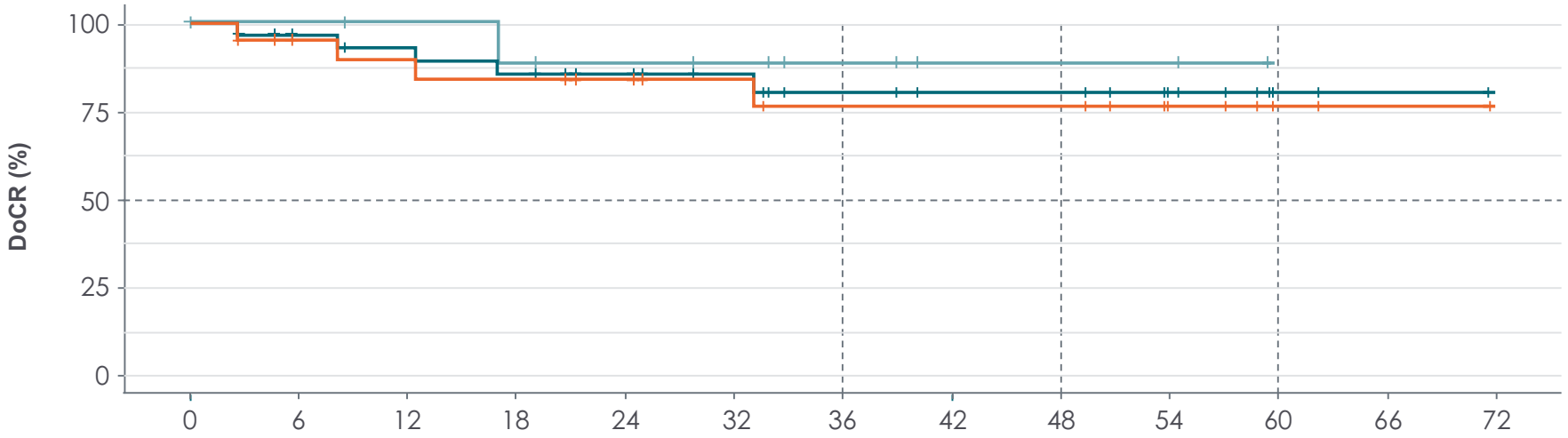
**L-MIND: Median duration of complete response (mDoCR)**
was not reached and suggests a plateau after approximately 12 months[1,a]

| Analysis | 5-year final: 14 Nov 2022 | | |
|---|---|---|---|
| | Overall | 2L | ≥3L |
| **mDoCR**, months [95% CI] | **NR** [NR, NR] | **NR** [31.0, NR] | **NR** [16.9, NR] |




Patients at risk

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Overall** | 33 | 27 | 25 | 23 | 20 | 17 | 13 | 11 | 11 | 7 | 2 | 1 | 0 |
| **2L** | 21 | 17 | 16 | 15 | 13 | 11 | 9 | 9 | 9 | 5 | 2 | 1 | 0 |
| **≥3L** | 12 | 10 | 9 | 8 | 7 | 6 | 4 | 2 | 2 | 2 | 0 | 0 | 0 |

**mFU, months [95% CI]**
**Overall 32.7** [24.4, 53.6]

**a** Median overall follow-up 32.7 months, Data cut-off November 2022

**CI:** confidence interval **DoCR:** duration of complete respons **mFU:** median follow-up **NR:** not reached **2L:** second line **3L:** third line

**1** Duell J et al.,Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480

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# 5-year Data: Efficacy Results - PFS

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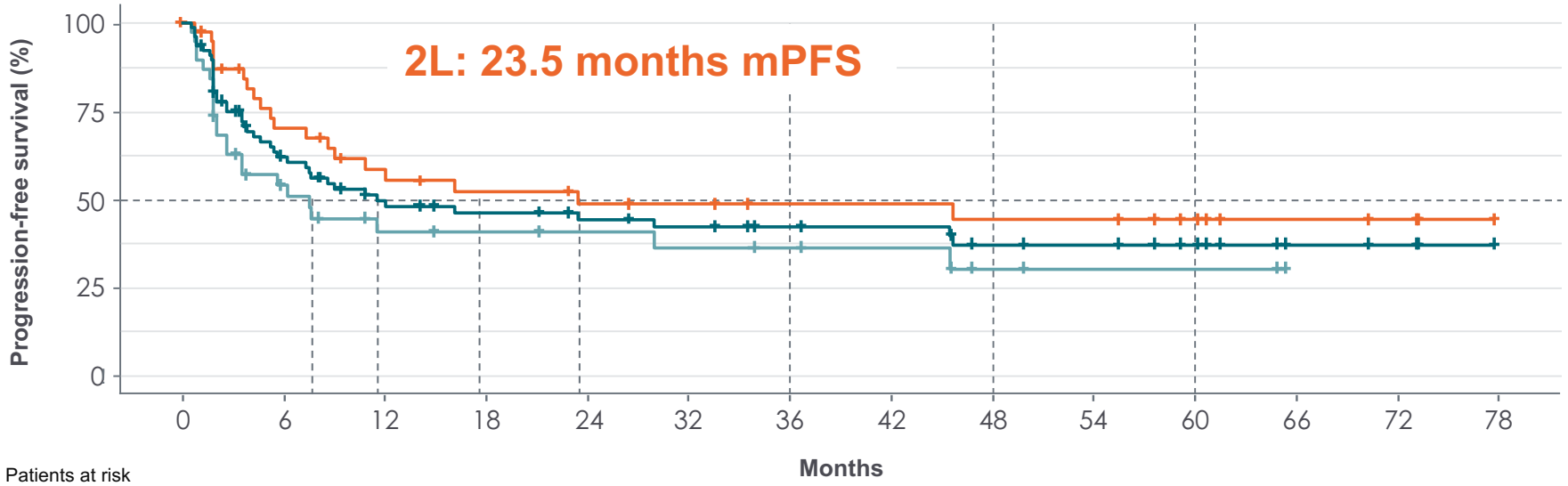
**L-MIND subgroup analysis: Median progression-free survival (mPFS) data** by number of prior therapies.[1,a]

| Analysis | 3-year [2] 30 Oct 2020 | 5-year final: 14 Nov 2022 | | |
|---|---|---|---|---|
| | | Overall | 2L | ≥3L |
| **mPFS**, months [95% CI] | 11.6 [6.3, 45.7] | **11.6** [5.7, 45.7] | **23.5** [7.4, NR] | **7.6** [2.7, 45.5] |




Patients at risk

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Overall** | 80 | 42 | 30 | 26 | 23 | 21 | 18 | 17 | 13 | 12 | 9 | 4 | 3 | 0 |
| **2L** | 40 | 25 | 19 | 16 | 14 | 13 | 11 | 11 | 10 | 10 | 7 | 4 | 3 | 0 |
| **≥3L** | 40 | 17 | 11 | 10 | 9 | 8 | 7 | 6 | 3 | 2 | 2 | 0 | 0 | 0 |

**mFU, months [95% CI]**
**Overall 45.6** [22.9, 57.6]

**a** Median overall follow-up 45.6 months, Data cut-off November 2022

**CI:** confidence interval **mFU:** median follow-up **mPFS:** median PFS **NR:** not reached **PFS:** progression-free survival **2L:** second line **3L:** third line


**1** Duell J et al., Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480 **2** Duell J et al., Long-term outcomes from the phase II L-MIND study of tafasitamab (MOR208) plus lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma. Haematologica. 2021; 106(9): 2417 – 26.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# 5-year Data: Efficacy Results - OS

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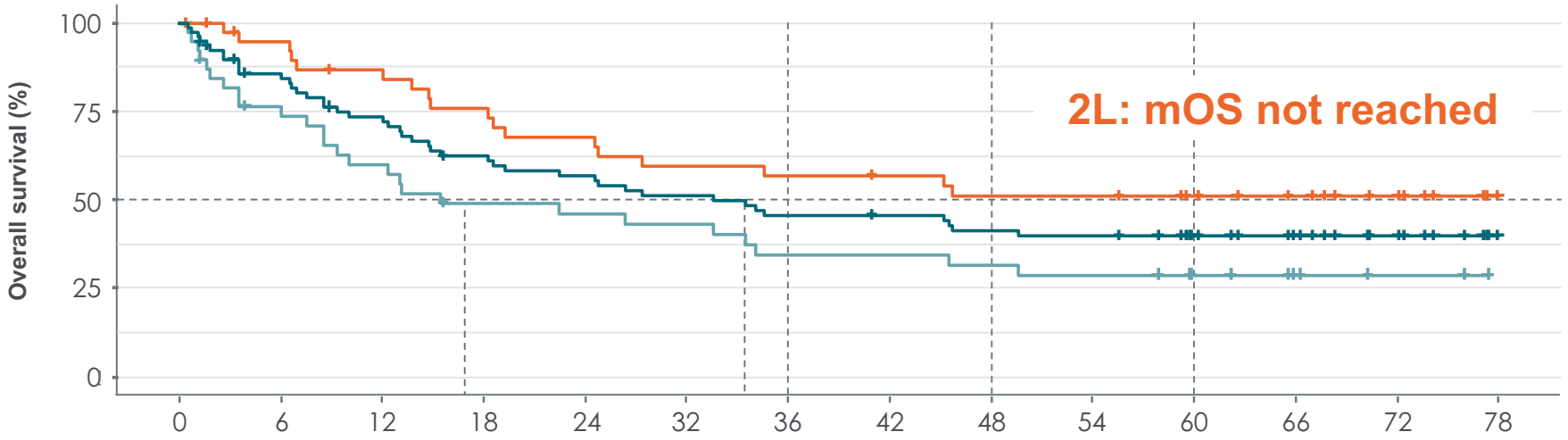
## L-MIND subgroup analysis: Median overall survival
by number of prior therapies[1,a]

| Analysis | 3-year[2] 30 Oct 2020 | 5-year final: 14 Nov 2022 | | |
|---|---|---|---|---|
| | | Overall | 2L | ≥3L |
| **mOS**, months [95% CI] | 33.5 [18.3, NR] | **33.5** [18.3, NR] | **NR** [24.6, NR] | **15.5** [8.6, 45.5] |




Patients at risk

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Overall** | 80 | 64 | 54 | 45 | 41 | 37 | 33 | 32 | 29 | 28 | 21 | 15 | 9 | 1 |
| **2L** | 40 | 36 | 32 | 28 | 25 | 22 | 21 | 20 | 18 | 18 | 14 | 11 | 7 | 1 |
| **≥3L** | 40 | 28 | 22 | 17 | 16 | 15 | 12 | 12 | 11 | 10 | 7 | 4 | 2 | 0 |

**mFU, months [95% CI]**
**Overall 65.6** [59.9, 70.3]

**a** Median overall follow-up 65.6 months, Data cut-off November 2022

**CI:** confidence interval **mFU:** median follow-up **mOS:** median OS **NR:** not reached **OS:** overall survival **2L:** second line **3L:** third line


**1** Duell J et al., Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480 **2** Duell J et al., Long-term outcomes from the phase II L-MIND study of tafasitamab (MOR208) plus lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma. Haematologica. 2021; 106(9): 2417 – 26.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# 5-year Data: OS according to Best Response in Patients with a CR or PR

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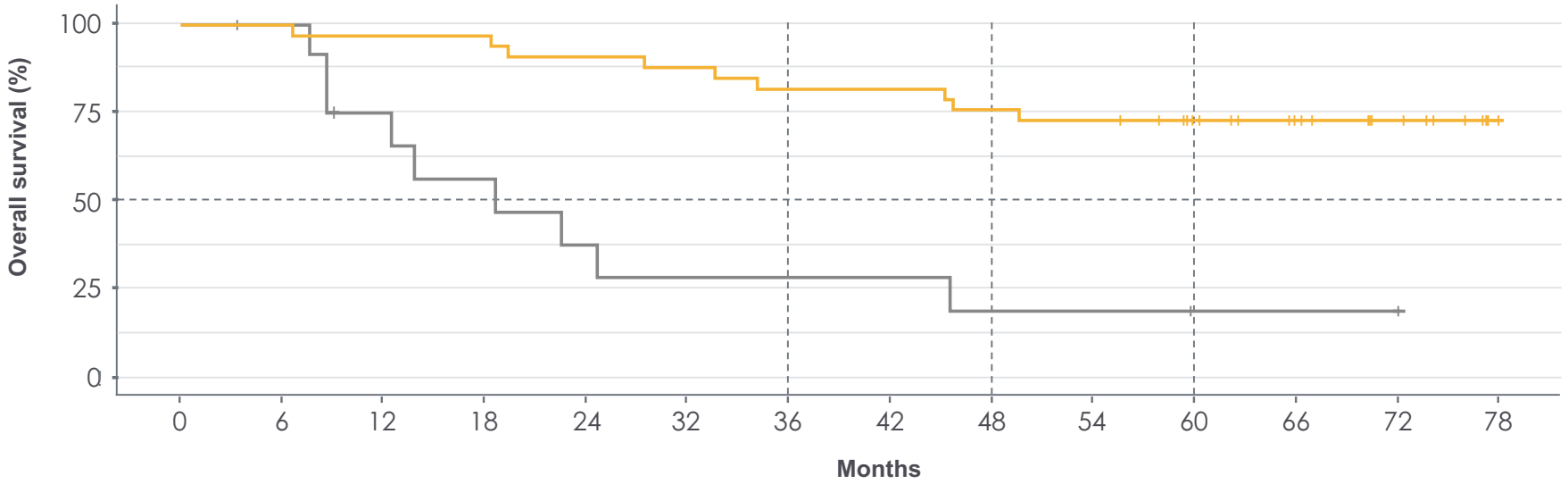
In patients with best response of CR, mOS was NR [95% CI: NR, NR],
and in patients with any response it was NR [45.5 months, NR]; by contrast, in patients with best response of PR, mOS was 18.6 months [95% CI: 8.6, 45.5][1]




| | mFU, months [95% CI] |
|---|---|
| CR | **66.1** [60.3, 72.4] |
| PR | **59.8** [9.0, NR] |

Patients at risk

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CR | 33 | 33 | 32 | 32 | 30 | 29 | 27 | 27 | 25 | 24 | 18 | 12 | 8 | 1 |
| PR | 13 | 12 | 8 | 6 | 4 | 3 | 3 | 3 | 2 | 2 | 1 | 1 | 1 | 0 |

Data cut-off November 2022

**CI:** confidence interval. **CR:** complete response. **mFU:** median follow-up. **mOS:** median OS. **NR:** not reached. **OS:** overall survival. **PR:** partial response.


**1** Duell J et al Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480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# Efficacy Results[1,a]

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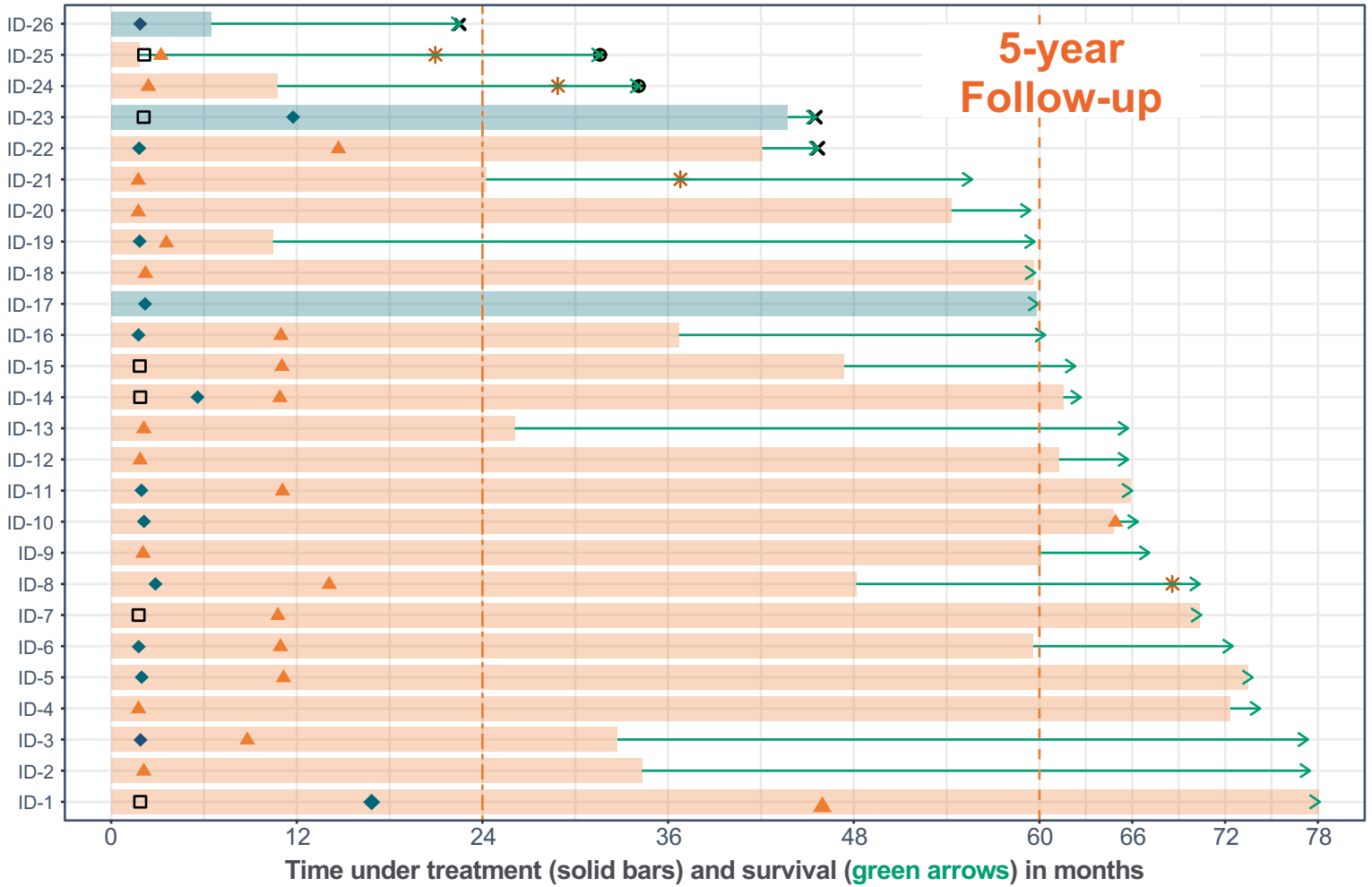


**25%** of the study population **was alive at final cut-off**

**Outcomes***
- Complete Response
- Partial Response
- Stable Disease
- Death from progressive disease
- Death from other reasons
- Next anti-lymphoma therapy

**Best Response**
- Complete Response
- Partial Response

*Repeat assessments giving the same outcome as previous assessment are not shown

**a** Follow-up of Patients who stopped treatment in response (n=26)

**1** Duell J et al., Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480

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# Subgroup Analysis of 5-Year Data: ORR in FAS Population and Subgroups[1]

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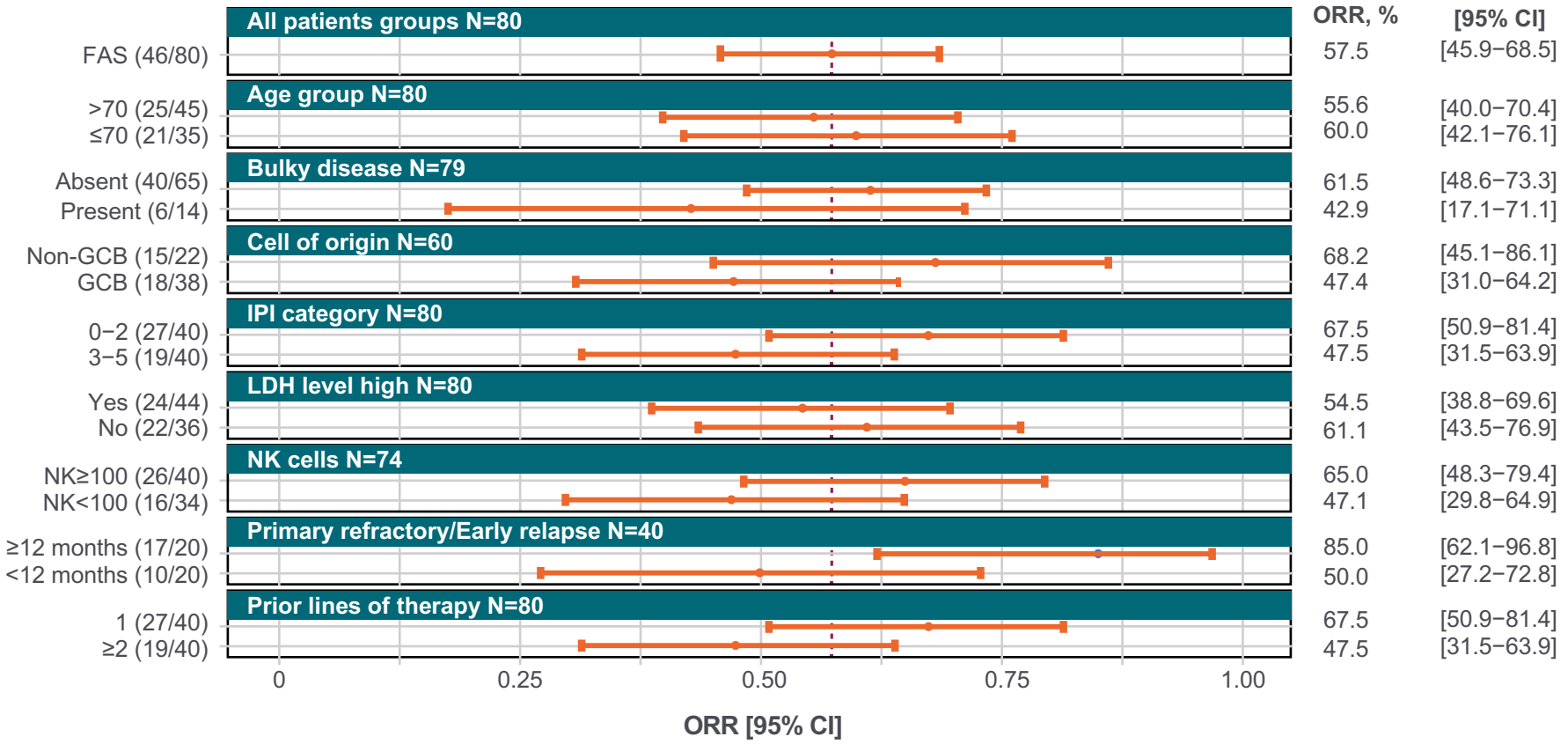


| | ORR, % | [95% CI] |
|---|---|---|
| FAS (46/80) | 57.5 | [45.9−68.5] |
| >70 (25/45) | 55.6 | [40.0−70.4] |
| ≤70 (21/35) | 60.0 | [42.1−76.1] |
| Absent (40/65) | 61.5 | [48.6−73.3] |
| Present (6/14) | 42.9 | [17.1−71.1] |
| Non-GCB (15/22) | 68.2 | [45.1−86.1] |
| GCB (18/38) | 47.4 | [31.0−64.2] |
| 0−2 (27/40) | 67.5 | [50.9−81.4] |
| 3−5 (19/40) | 47.5 | [31.5−63.9] |
| Yes (24/44) | 54.5 | [38.8−69.6] |
| No (22/36) | 61.1 | [43.5−76.9] |
| NK≥100 (26/40) | 65.0 | [48.3−79.4] |
| NK<100 (16/34) | 47.1 | [29.8−64.9] |
| ≥12 months (17/20) | 85.0 | [62.1−96.8] |
| <12 months (10/20) | 50.0 | [27.2−72.8] |
| 1 (27/40) | 67.5 | [50.9−81.4] |
| ≥2 (19/40) | 47.5 | [31.5−63.9] |

**ORR was generally comparable between subgroups of clinical interest. However, ORR numerically favored patients with positive prognostic factors, such as lack of bulky disease, lower IPI score, 2L, and late relapse[a]**

**a** Late relapse was defined as time to relapse/PD ≥12 months after first line therapy, and its influence was investigated only in the subgroup of patients in second line.

**CI:** confidence interval **FAS:** full analysis set **GCB:** germinal centre B-cell **IPI:** International Prognostic Index **LDH:** lactate dehydrogenase **LEN:** lenalidomide **NK:** natural killer **ORR:** objective response rate **2L:** second line

**1** Duell J et al.,Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480

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# L-MIND: Safety results[1]

TEAES occurring in ≥20% of patients (all-grades safety analysis set)

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| | n, % |
|---|---|
| **Haematological** | |
| Neutropenia | 40 (49.4%) |
| Anaemia | 30 (37.0%) |
| Thrombocytopenia | 23 (28.4%) |
| **Non-haematological** | |
| Diarrhoea | 30 (37.0%) |
| Cough | 24 (29.6%) |
| Asthenia | 21 (25.9%) |
| Oedema peripheral | 20 (24.7%) |
| Pyrexia | 19 (23.5%) |
| Decreased appetite | 18 (22.2%) |

Most TEAEs of interest were hematological events during combination treatment

**Low incidence of infusion-related reactions and grade ≥3 infections and infestations**

**TEAE**: treatment-emergent adverse event

**1** Duell J et al., Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480

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# L-MIND: Safety results[1]

Exposure-Adjusted Comparison of TEAE Frequency across Treatment Periods

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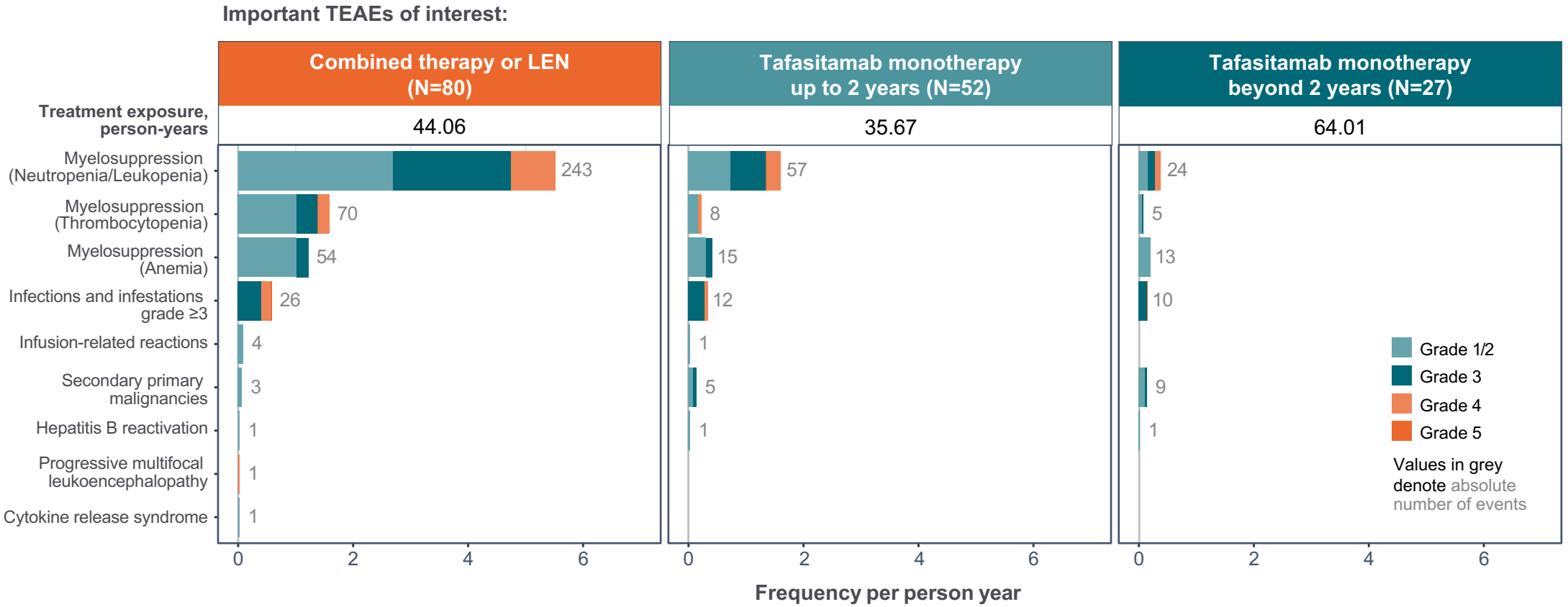


**CTCAE grading system LEN:** lenalidomide **TEAE**: treatment-emergent adverse event


**1** Duell J et al., Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024;109(2):553–566. doi: 10.3324/haematol.2023.283480


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# Real-World Evidence (US): Best Response[1]

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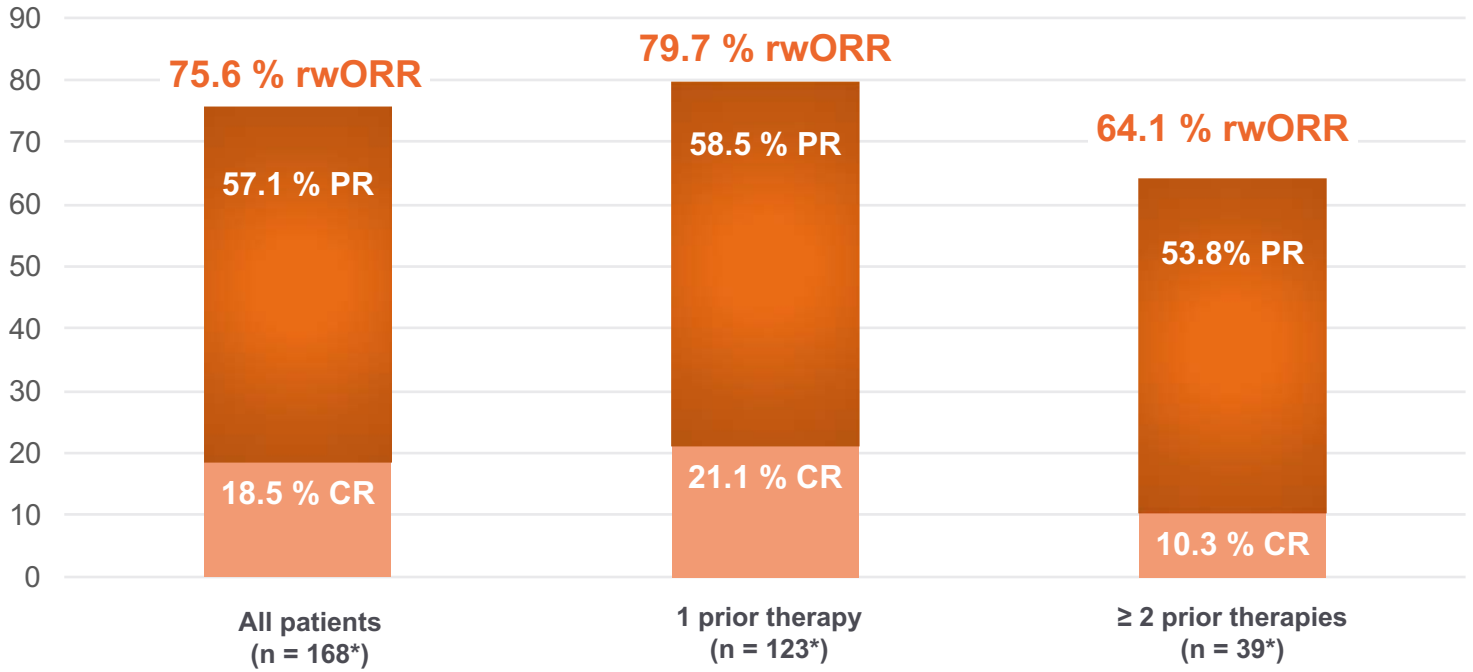
- This real-world study included 181 R/R DLBCL-patients treated with Tafasitamab.
- The patients were followed for a minimum of 4 months[a] and a median of 6.5 months.
  Longer follow-up of these patients is needed to better understand long-term outcomes of tafasitamab in real world.**




**High overall response rates observed in L-MIND are confirmed in this patient population with a response in almost 80% of patients treated in 2L.[b]**

**a** Otherwise eligible patients who died during this 4-month interval were still eligible. Data collection in Q1 2023
**b** 79.7%

*Patient denominators represent those with available best disease response data. **Median time to CR in L-MIND was 8.1 months.
**rwORR:** real-world overall response rate **R/R DLBCL:** relapsed or refractory diffuse large B-cell lymphoma **CR:** complete remission **PR:** partial remission **2L:** second line
Response criteria used for assessing best response (% among those with best response available) included: Cheson 2007 (26.8%), Lugano (72.6%), and other (0.6%)

**1** Kim Saverno et al., Tafasitamab for the Treatment of Relapsed or Refractory Diffuse Large B-Cell Lymphoma in the US Real-World Setting; Oral presentation 265 at ASH Dec 2023; https://www.incytemi.com/document/Poster/ASH%202023%20-%20Tafasitamab%20RWE%20(oral%20presentation).pdf

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# EarlyMIND: LARGEST EUROPEAN RWE FOR TAFA+LEN

Retrospective multicenter analysis of Incyte's 'Early Access Program' in France for R/R DLBCL patients[1]

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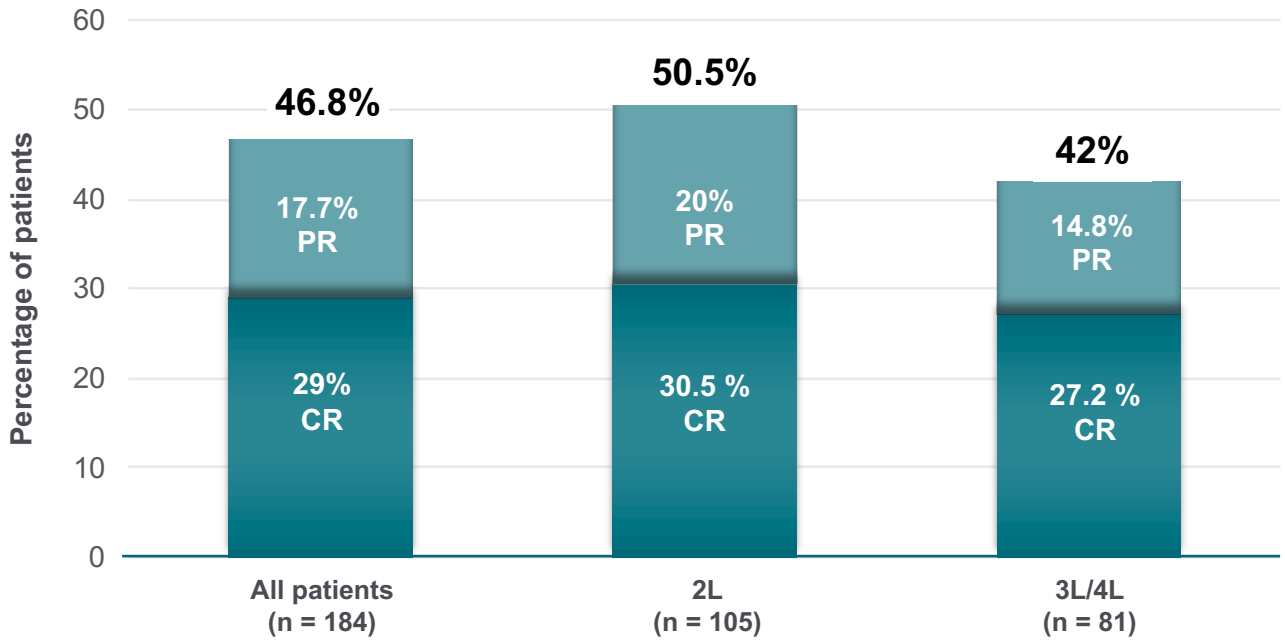
## Best Objective Response (bOR)




## In 2L, every second patient responded to Tafa+LEN

- **mFU: 8.2 months**
- **The mOS, mPFS and mDOR were not significantly different between the cohorts**

  **mOS: 10.0 mo**
  Cohort A: 10.6 mo / Cohort B: 8.2 mo

  **mPFS: 4.7 mo**
  Cohort A: 5.4 mo / Cohort B: 3.6 mo

  **mDOR: 13.4 mo**
  Cohort A: 12.2 mo / Cohort B: not reached

**CR:** complete remission **PR:** partial remission **2L:** 2nd line **3L:** 3rd line **4L:** 4th line **mFU:** median follow-up; **mDOR:** median duration of response **mOS:** median overall survival **mPFS:** median progression-free survival **TAFA+LEN:** Tafasitamab + Lenalidomide

Patients included in the Tafasitamab+Leanalidomide early access program in France between January, 2022 and March, 2023.

**1** Herbaux et al, Poster 1214; Poster 1214; EarlyMIND, a Retrospective Multicenter Study in Real-World Settings to Characterize Tafasitamab-Lenalidomide Efficacy in Transplant-Ineligible Patients With Relapsed/Refractory Large B-Cell Lymphoma; presented during EHA 2024, June 2024 presented during EHA 2024, June 2024

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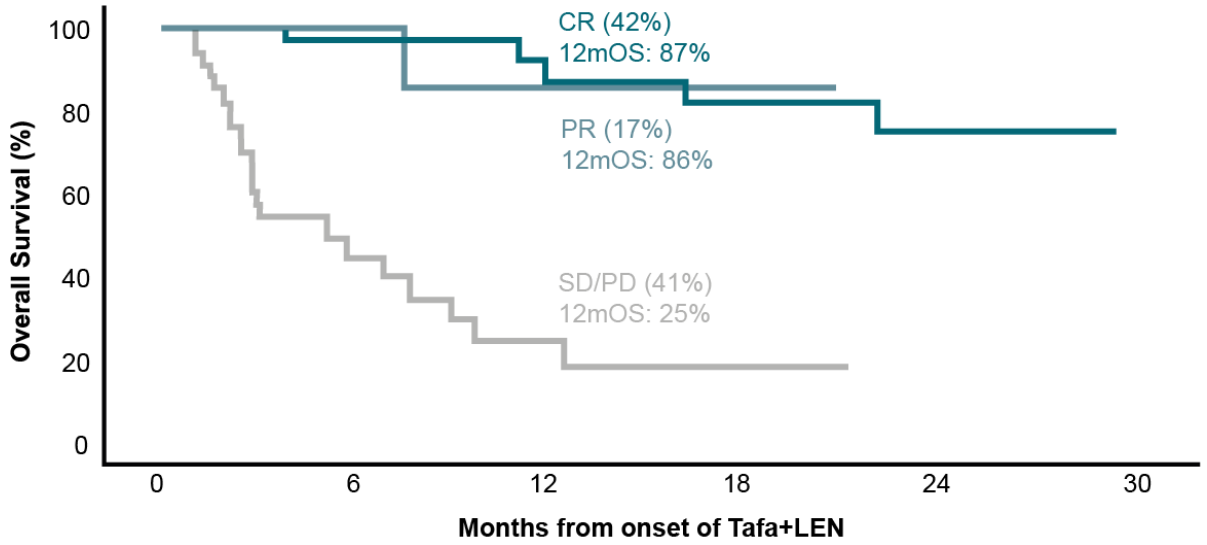
# EUROPEAN RWE FOR TAFA+LEN FROM SPAIN

Retrospective multicenter analysis of RWE data from the Spanish Lymphoma Group (Geltamo) for R/R DLBCL patients*[1]

MINJUVI® tafasitamab

## Overall Survival (OS) per Response Type




- **mOS was not reached in patients who responded to treatment**
- **2 out of 3 patients were still alive at data collection**

- **mFU: 9.4 months**
- **mOS: not reached**
- **mPFS: 10.9 mo**
- **mDOR**
  for patients with CR: not reached
  for patients with PR: 6.8 months

**CR:** complete response **PR:** partial response **SD:** stable disease **PD:** progressive disease **mFU:** median follow-up **mDOR:** median duration of response **mOS:** median overall survival **mPFS:** median progression-free survival **RWE:** real world evidence **Tafa+LEN:** tafasitamab plus lenalidomide

*Patients included in the Tafa+LEN early access program in Spain between June 2021 and December 2023. Medium follow-up was 9.4 months.

**1** Gutiérrez et al, Poster 1203; Tafasitamab plus lenalidomide as salvage therapy in DLBCL: the Spanish Group of Lymphoma (GELTAMO) real-world experience; presented during EHA 2024, June 2024

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# Dosing schedule Tafasitamab + Lenalidomide[1]

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### Cycle 1

| Day | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Tafasitamab 12 mg/kg** | ■ | | | ■ | | | | ■ | | | | | | | ■ | | | | | | | ■ | | | | | | |
| Lenalidomide 25 mg/d | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | | | | | | | |

### Cycle 2 – 3

| Day | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Tafasitamab 12 mg/kg** | ■ | | | | | | | ■ | | | | | | | ■ | | | | | | | ■ | | | | | | |
| Lenalidomide 25 mg/d | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | | | | | | | |

### Cycle 4 – 12

| Day | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Tafasitamab 12 mg/kg** | ■ | | | | | | | | | | | | | | ■ | | | | | | | | | | | | | |
| Lenalidomide 25 mg/d | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | | | | | | | |

### Cycle 13 onwards

| Day | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Tafasitamab 12 mg/kg** | ■ | | | | | | | | | | | | | | ■ | | | | | | | | | | | | | |

**After a maximum of 12 cycles of combination therapy, MINJUVI should be continued as monotherapy until progression or unacceptable toxicity.[1]**


1 MINJUVI Professional Information. see www.swissmedicinfo.ch

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# Conclusions[1]

MINJUVI® tafasitamab

- **5-year L-MIND Follow-up** confirms the rapid and **durable disease control** and **long-term survival**, particularly at 2L[1]
  - Almost 75% of complete responders were still alive at 5 years[1]
  - Every second patient responded with a CR when treated in 2L[1,a]
  - mDoR was not reached after 44 months of median follow-up - irrespective of treatment line[1]
- **Real world evidence data supported the overall response rate**, especially when used in early lines of treatment.[2]
- **No new safety signals** were identified, confirming the tolerable safety profile[1]

  The observed adverse events continue to decrease in the further course of monotherapy with Tafasitamab (≥ 2 years).[1]

**a:** 52.5%; **CR:** complete remission **mDoR:** median duration of response **2L:** second line

**1** Duell J et al., Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study; Haematologica. 2024; 109(2):553–566. doi: 10.3324/haematol.2023.283480 **2** Kim Saverno et al., Tafasitamab for the Treatment of Relapsed or Refractory Diffuse Large B-Cell Lymphoma in the US Real-World Setting; Oral presentation 265 at ASH Dec 2023; https://www.incytemi.com/document/Poster/ASH%202023%20-%20Tafasitamab%20RWE%20(oral%20presentation).pdf

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MINJUVI®
tafasitamab

▼ This medicinal product is subject to additional monitoring. For further information, see professional information MINJUVI on www.swissmedicinfo.ch.

**MINJUVI (tafasitamab), 200 mg powder for concentrate for solution for infusion.**

**I:** MINJUVI is indicated in combination with lenalidomide followed by MINJUVI monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after at least one line of systemic CD20-targeted antibody therapy who are not eligible for autologous stem cell transplantation (ASCT). **P:** MINJUVI must be administered by a healthcare professional experienced in treatment of cancer patients. The recommended dose is 12 mg of MINJUVI per kg body weight administered as an intravenous infusion. On cycles 1-3: Administer on days 1, 8, 15 and 22 with an additional dose on day 4 of cycle 1. From cycle 4 onwards: Administer on day 1 and 15 of each cycle. In addition, patients should self-administer lenalidomide capsules at the recommended starting dose of 25 mg daily on days 1 to 21 of each 28-day cycle for a maximum of 12 cycles. Dose adjustments due to adverse reactions are needed. **CI:** Hypersensitivity to tafasitamab or any of the excipients. **W/P:** Infusion-related reactions may occur. Patients should be monitored closely throughout infusion. Treatment can cause serious and/or severe myelosuppression. Monitor complete blood counts throughout treatment and prior to administration of each treatment cycle. Withhold MINJUVI based on the severity of the adverse reaction. Fatal and serious infections occurred. Monitor patients for symptoms and signs of progressive multifocal leukoencephalopathy (PML); suspend treatment in case of suspected PML. Administer MINJUVI to patients with an active infection only if the infection is treated appropriately and well controlled. Monitor patients closely for tumor lysis syndrome. QTc prolongation and syncopes have been observed during treatment with MINJUVI. MINJUVI can cause fetal harm. Women of childbearing potential should be advised not to become pregnant during treatment. **IA:** No interaction studies have been performed for tafasitamab. **UE:** The most common adverse reactions (≥ 20%) were infections, asthenia, neutropenia, anaemia, thrombocytopenia and diarrhea. The most common serious adverse reactions (≥ 3 %) were febrile neutropenia and pneumonia. For further information on UE, see www.swissmedicinfo.ch. **Dispensing cat.:** A. **Revision date:** May 2024. **Marketing authorisation holder:** Incyte Biosciences International Sàrl, CH-1110 Morges. MINJUVI and the “triangle” design are (registered) trademarks of Incyte. Refer to www.swissmedicinfo.ch for detailed information.

All references are available upon request.


CH/MJVI/P/24/0005 Version 2: 07/2024

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