
















# 6 Durable Responses With Mosunetuzumab in Relapsed/Refractory Indolent and Aggressive B-Cell Non-Hodgkin Lymphomas: Extended Follow-Up of a Phase I/II Study

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## ABSTRACT

*Clinical trials frequently include multiple end points that mature at different times. The initial report, typically based on the primary end point, may be published when key planned co-primary or secondary analyses are not yet available. Clinical Trial Updates provide an opportunity to disseminate additional results from studies, published in JCO or elsewhere, for which the primary end point has already been reported.*

Mosunetuzumab is a CD20xCD3 T-cell–engaging bispecific antibody administered as an off-the-shelf, fixed-duration treatment in an outpatient setting. We report an updated analysis of the durability of response, by investigator assessment, after an overall median follow-up of 3.5 years in patients with relapsed/refractory indolent or aggressive B-cell non-Hodgkin lymphoma (iNHL/aNHL) from the dose-escalation stage of a phase I/II study of mosunetuzumab (ClinicalTrials.gov identifier: [NCT02500407](https://clinicaltrials.gov/ct2/show/study/NCT02500407)). Across dose levels, 65.7% of patients with iNHL and 36.4% with aNHL achieved a complete or partial response to mosunetuzumab. Median duration of response (DoR) in patients with iNHL for all responders was 23.2 months (95% CI, 13.8 to not estimable [NE]), but was not reached in complete responders (95% CI, 21.0 to NE). After a median time on study of 38.9 months, no relapses were observed beyond 26 months in complete responders. In patients with aNHL, median DoR for all responders was 7.8 months (95% CI, 4.6 to 22.8). Among 12 complete responders who progressed postmosunetuzumab treatment and were retreated with mosunetuzumab, 83.3% had an objective response and 58.3% achieved a second complete response. Our study reports the longest follow-up using bispecific antibodies in patients with B-cell non-Hodgkin lymphoma and demonstrates that mosunetuzumab can mediate durable remissions with time-limited treatment.

## INTRODUCTION

Mosunetuzumab is a CD20xCD3 T-cell–engaging bispecific antibody that engages and redirects T cells to eliminate malignant B cells. It is an off-the-shelf treatment that can be administered as an outpatient regimen and has been granted conditional marketing authorization by the European Medicines Agency and accelerated approval by the US Food and Drug Administration for the treatment of relapsed or refractory (R/R) follicular lymphoma (FL) in patients who have received  $\geq 2$  previous lines of therapy.<sup>1-5</sup> Mosunetuzumab is undergoing further development for the treatment of both indolent and aggressive B-cell non-Hodgkin lymphoma (iNHL and aNHL, respectively). Our initial report from the dose-escalation phase of the first-in-human trial (ClinicalTrials.gov identifier: [NCT02500407](https://clinicaltrials.gov/ct2/show/study/NCT02500407))

demonstrated that single-agent mosunetuzumab administered by step-up dosing had a manageable safety profile and induced durable complete responses (CRs) in patients with R/R NHL.<sup>5,6</sup> Here, we report an updated analysis with a median follow-up time of 3.5 years. This analysis evaluates the long-term efficacy and safety outcomes of mosunetuzumab, as well as the re-treatment experience across lines of treatment.

## METHODS

[NCT02500407](https://clinicaltrials.gov/ct2/show/study/NCT02500407) is a phase I/II, multicenter, open-label, dose-escalation and expansion study in patients with R/R NHL. The study design has been described previously.<sup>5,6</sup> Further details, including dosing schedules, are provided in the Data Supplement (online only).

## ACCOMPANYING CONTENT

-  [Data Supplement](#)
-  [Protocol](#)

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This analysis examines the durability of response to mosunetuzumab as assessed by investigators, with an additional 2 years of follow-up since the previous data cutoff (January 21, 2020–January 3, 2022), with a median follow-up of 3.5 years (range, 2.7–6.3; from enrollment to January 3, 2022). Survival outcomes and safety were also examined.

All enrolled patients provided written informed consent. The Protocol (online only) was approved by institutional review boards at each center and the trial was conducted in accordance with the Declaration of Helsinki, International Conference on Harmonisation Guidelines for Good Clinical Practice, and appropriate laws and regulations.

## RESULTS

### Patients

Thirty-three patients were enrolled in group A (0.05–2.8 mg) and 196 patients in group B (0.4/1.0/2.8–1.0/2.0/60.0 mg [cycle 1, day 1/8/15]; iNHL, n = 67; aNHL, n = 129) from September 2015 to May 2019. As of the clinical cutoff date (CCOD; January 3, 2022), median time on study was 12.5 months (range, 0.7–74.8) in group A and 12.6 months (range, 0.3–62.4) in group B.

Baseline patient and disease characteristics are reported in [Table 1](#). At CCOD, 9/33 (27.3%) and 73/196 (37.2%) patients from group A and B, respectively, remained on the study in follow-up (Data Supplement, Fig S1).

### Response Rate and Durability of Response

When assessed by an investigator (with or without positron emission tomography), 6/33 (18.2%) patients in group A had an objective response, with 4/33 (12.1%) patients achieving a CR as best response. The duration of response (DoR) in the four complete responders was 26.0 and 46.2 months (ongoing) in the two patients with iNHL and 43.2 (ongoing at the time of withdrawal of consent) and 18.7 months in the two patients with aNHL (Data Supplement, Fig S2).

In group B, 44/67 (65.7%) patients with iNHL and 47/129 (36.4%) patients with aNHL achieved a response ([Table 2](#)). In patients with iNHL, the median DoR was 23.2 months (95% CI, 13.8 to not estimable [NE]) for all responders (n = 44) and not reached (NR) (95% CI, 21.0 to NE) in complete responders (n = 33; [Fig 1A](#)). With a median time on study of 38.9 months (range, 10.2–61.0), no relapses were observed beyond 26 months in patients with iNHL with a CR. In patients with aNHL, the median DoR was 7.8 months (95% CI, 4.6 to 22.8) for all responders (n = 47) and 28.8 months (95% CI, 11.5 to NE) for complete responders (n = 28; [Table 2](#); [Fig 1B](#)). In patients with iNHL or aNHL and a partial response (PR), the median DoR was 7.8 months (95% CI, 4.3 to 8.7) and 3.3 months (95% CI, 2.6 to 4.6), respectively ([Table 2](#); Data Supplement, Fig S3).

Twelve patients in group B (iNHL, n = 8; aNHL, n = 4) who had a CR with initial mosunetuzumab treatment and then

progressed were retreated with fixed-duration mosunetuzumab. Best response and DoR with retreatment are outlined in [Table 2](#) and the Data Supplement (Table S1). During retreatment, 10/12 (83.3%) patients had an objective response, with 7/12 (58.3%) patients achieving a CR.

### Long-Term Survival Outcomes

Survival outcomes for group B are detailed in [Table 2](#) and the Data Supplement (Figs S4–S6). In patients with iNHL, the 36-month progression-free survival (PFS) rate was 29.7% (95% CI, 17.9 to 41.5).

In patients with aNHL, the 36-month PFS rate was 10.3% (95% CI, 3.8 to 16.8).

A summary of patient deaths is outlined in the Data Supplement.

### Safety

A summary of adverse events (AEs) is provided in the Data Supplement (Table S2). Eight additional AEs were reported in six patients from group B (Data Supplement, Table S3) since the previous CCOD (January 21, 2020).<sup>5</sup> No new safety concerns were identified.

## DISCUSSION

We report an updated analysis of this first-in-human study of mosunetuzumab with a median follow-up of 3.5 years, which, to our knowledge, is the longest reported follow-up of any series of patients treated with a CD20xCD3 bispecific antibody. In the dose-escalation cohorts of group B, the median DoR in all responders was 23.2 and 7.8 months in patients with iNHL and aNHL, respectively. Responses induced by mosunetuzumab were more durable in patients with CR compared with those with PR. We hypothesize that the shorter DoR in patients with aNHL versus patients with iNHL may have been driven by the lower CR rate observed in aNHL compared with iNHL.

In patients who achieved a CR, responses were durable in both aNHL and iNHL. Importantly, these sustained complete remissions were achieved in the absence of continuous treatment. Furthermore, the effectiveness of mosunetuzumab retreatment, with a significant proportion of retreated patients achieving a CR, supports a fixed-duration treatment approach. These findings also suggest that mosunetuzumab could potentially be incorporated into multiple lines of treatment.

Although the median DoR for mosunetuzumab monotherapy in the dose-escalation cohorts for iNHL was lower than that observed in the FL expansion cohort at the recommended dose (NR [range, 21 months–NE]),<sup>7</sup> it compares favorably with that of other approved therapies for R/R FL. A median DoR of 10.9 months was reported with tazemetostat

**TABLE 1.** Demographics, Baseline Disease Characteristics, and Treatment Exposure of Patients in Groups A and B

Characteristic	Group A (n = 33)	Group B	
		iNHL (n = 67)	aNHL (n = 129)
Age, years, median (range)	64 (30-84)	60 (27-85)	64 (19-91)
Male, No. (%)	20 (60.6)	42 (62.7)	82 (63.6)
ECOG PS at baseline, No. (%)			
0	12 (36.4)	37 (55.2)	41 (31.8)
1	21 (63.6)	30 (44.8)	87 (67.4)
2	0	0	1 (0.8)
B-NHL subtype at study entry, No. (%)			
DLBCL	14 (42.4)	0	79 (61.2)
FL	9 (27.3)	64 (95.5)	0
trFL	5 (15.2)	0	29 (22.5)
MCL	2 (6.1)	0	13 (10.1)
Other	3 (9.1) <sup>a</sup>	3 (4.5) <sup>b</sup>	8 (6.2) <sup>c</sup>
Ann Arbor stage at study entry, No. (%)			
I-II	4 (12.1)	9 (13.4)	19 (14.7)
III-IV	29 (87.9)	58 (86.5)	110 (85.3)
Time from last prior therapy to mosunetuzumab, months, median (range)	2.8 (1-46)	3.2 (0-61)	2.0 (0-137)
No. of prior lines of therapy, median (range)	3 (1-9)	3 (1-9)	3 (1-14)
Prior cancer therapies, No. (%)			
Anti-CD20 antibody	33 (100)	67 (100)	129 (100)
Anthracycline	26 (78.8)	46 (68.7)	127 (98.4)
Alkylator therapy	32 (97.0)	67 (100)	129 (100)
CAR T-cell therapy	0 (0)	4 (6.0)	15 (11.6)
ASCT	7 (21.2)	9 (13.4)	33 (25.6)
Relapsed/refractory <sup>d</sup> status, No. (%)			
Refractory to any prior therapy	30 (90.9)	59 (88.1)	124 (96.1)
Refractory to last prior therapy	27 (81.8)	50 (74.6)	113 (87.6)
Refractory to prior anti-CD20	27 (81.8)	57 (85.1)	107 (82.9)
Refractory to prior CAR T-cell	0 (0)	3 (4.5)	12 (9.3)
Follow-up, years, median (range)	5.5 (4.9-6.3)	3.3 (2.7-5.2)	3.4 (2.7-5.2)
Mosunetuzumab treatment duration, months, median (range)	2.1 (0-5.3)	4.9 (0-11.8)	1.6 (0-12.0)
No. of mosunetuzumab treatment cycles, median (range)	4 (1-8)	8 (1-17)	3 (1-17)

Abbreviations: aNHL, aggressive B-cell non-Hodgkin lymphoma; ASCT, autologous stem-cell transplantation; B-NHL, B-cell non-Hodgkin lymphoma; CAR, chimeric antigen receptor; DLBCL, diffuse large B-cell lymphoma; ECOG PS, Eastern Cooperative Oncology Group performance status; FL, follicular lymphoma; FL3b, follicular lymphoma, grade 3b; iNHL, indolent B-cell non-Hodgkin lymphoma; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; RS, Richter's transformation; SLL, small lymphocytic lymphoma; trFL, transformed follicular lymphoma; trMZL, transformed marginal zone lymphoma.

<sup>a</sup>MZL (n = 1); RS (n = 1); SLL (n = 1).

<sup>b</sup>MZL (n = 2); SLL (n = 1).

<sup>c</sup>DLBCL/MCL (n = 1); FL3b (n = 1); RS (n = 5); trMZL (n = 1).

<sup>d</sup>Defined as not achieving a response (complete or partial) or progressing within ≤6 months of applicable treatment.

monotherapy in the mutant EZH2 cohort (n = 45) of a phase II trial,<sup>8</sup> while the median DoR with copanlisib was 14.1 months in the phase II CHRONOS-1 study of patients (N = 142) with R/R indolent B-cell lymphoma who had received ≥2 previous treatments.<sup>9</sup> Notably, in the current analysis, the median DoR in patients with iNHL who achieved CR was NR; this outcome is similar to that observed with axicel in the ZUMA-5 study of patients with R/R iNHL after >3 years of follow-up.<sup>10</sup>

The wide range of doses explored in this dose-escalation study, and potential differences in patient populations and trial designs, preclude direct comparisons of our results in patients with aNHL with those from previous phase II studies in patients with R/R diffuse large B-cell lymphoma. Nonetheless, the observed CR rate for mosunetuzumab in aNHL in this study (21.7%) was similar to that achieved with approved therapies, such as loncastuximab teserine (CR rate, 24.1%).<sup>11</sup> While response rates in aNHL appear lower

**TABLE 2. Summary of Efficacy in Patients With iNHL and aNHL Who Were Initially Treated or Retreated With Mosunetuzumab (group B)**

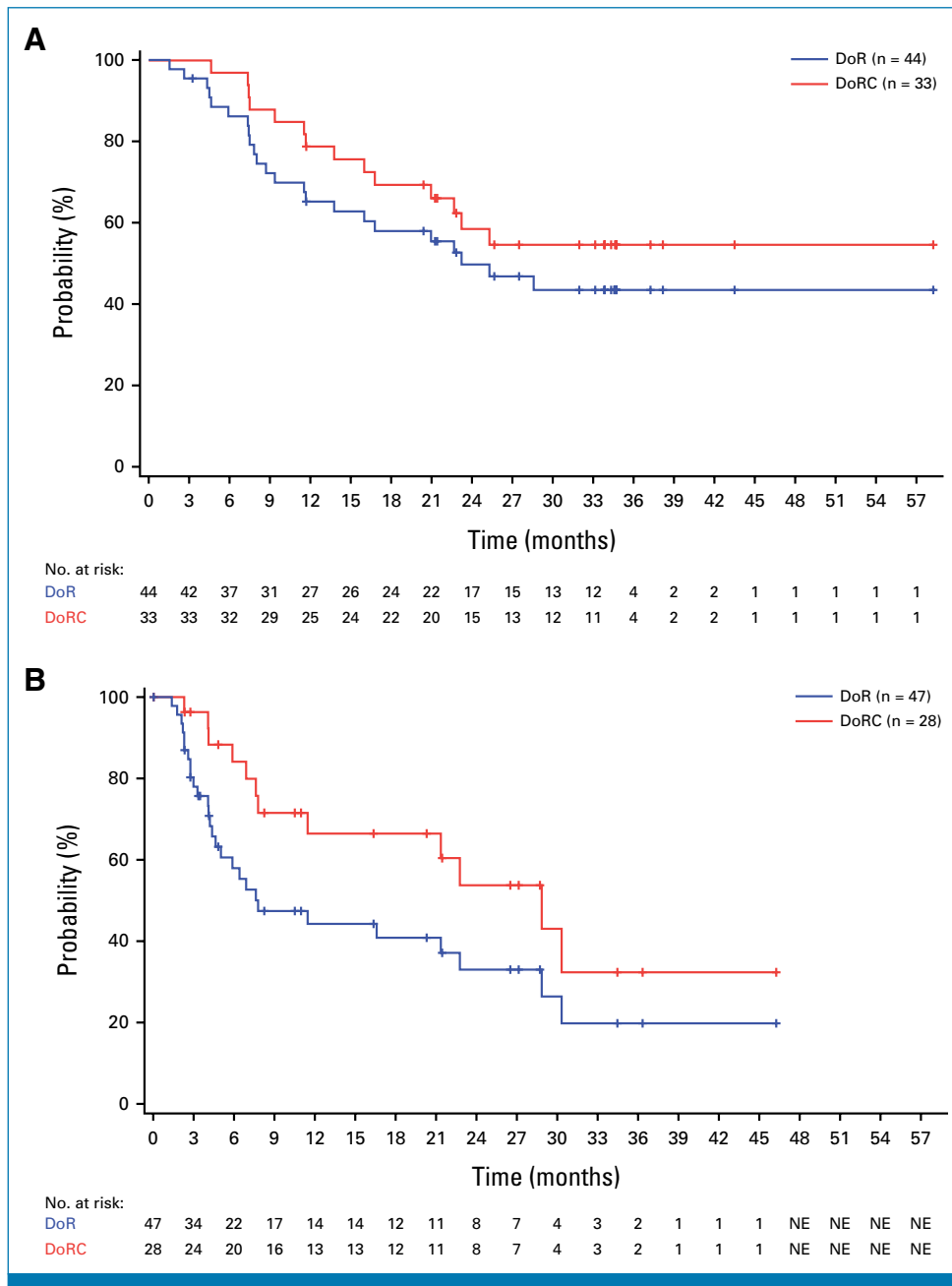
Efficacy End Point	iNHL (n = 67)	aNHL (n = 129)
Initial mosunetuzumab treatment		
Best overall response ( $\pm$ PET), No. (%)		
ORR	44 (65.7)	47 (36.4)
CR	33 (49.3)	28 (21.7)
PR	11 (16.4)	19 (14.7)
Duration of response		
Overall	n = 44	n = 47
Months, median (95% CI)	23.2 (13.8 to NE)	7.8 (4.6 to 22.8)
K-M event-free rate, % (95% CI)		
24 months	49.7 (34.4 to 65.1)	33.0 (16.9 to 49.1)
36 months	43.5 (27.7 to 59.2)	19.8 (2.7 to 36.9)
CR patients	n = 33	n = 28
Months, median (95% CI)	NR (21.0 to NE)	28.8 (11.5 to NE)
K-M event-free rate, % (95% CI)		
24 months	58.5 (40.9 to 76.0)	53.6 (31.4 to 75.9)
36 months	54.6 (36.6 to 72.5)	32.2 (5.6 to 58.8)
PR patients	n = 11	n = 19
Months, median (95% CI)	7.8 (4.3 to 8.7)	3.3 (2.6 to 4.6)
Progression-free survival		
Overall	n = 67	n = 129
Months, median (95% CI)	12.2 (8.4 to 24.0)	1.4 (1.4 to 2.8)
K-M event-free rate, % (95% CI)		
24 months	39.7 (27.7 to 51.8)	15.0 (8.3 to 21.7)
36 months	29.7 (17.9 to 41.5)	10.3 (3.8 to 16.8)
Overall survival		
Overall	n = 67	n = 129
Months, median (95% CI)	NR (NE)	9.4 (6.7 to 17.5)
K-M event-free rate, % (95% CI)		
24 months	85.5 (76.7 to 94.3)	34.2 (25.2 to 43.1)
36 months	82.0 (72.3 to 91.7)	29.3 (20.7 to 37.9)
Time to next treatment		
Overall	n = 67	n = 129
Months, median (95% CI)	31.3 (11.3 to NE)	4.4 (3.5 to 5.6)
K-M event-free rate, % (95% CI)		
24 months	58.4 (46.1 to 70.7)	16.9 (9.7 to 24.1)
36 months	46.2 (33.0 to 59.4)	14.2 (7.2 to 21.2)
Mosunetuzumab re-treatment <sup>a</sup>		
Best overall response ( $\pm$ PET), No. (%)		
ORR	n = 8	n = 4
ORR	7 (87.5)	3 (75.0)
CR	5 (62.5)	2 (50.0)
PR	2 (25.0)	1 (25.0)

Abbreviations: aNHL, aggressive B-cell non-Hodgkin lymphoma; CR, complete response; iNHL, indolent B-cell non-Hodgkin lymphoma; K-M, Kaplan-Meier; NE, not estimable; NR, not reached; ORR, objective response rate; PET, positron emission tomography; PR, partial response.

<sup>a</sup>Additional details are provided in the Data Supplement (Table S1).

than with other CD20xCD3 bispecific antibodies and CD19-targeting chimeric antigen receptor-T therapies, the median DoR with mosunetuzumab exceeded 28 months in patients with CR, which is similar to response durations

reported with these therapies.<sup>12-14</sup> Limitations of this study are the small sample size for some dose cohorts, which makes analysis by different doses challenging; and the use of the Cheson 2007 response criteria for efficacy



**FIG 1.** Kaplan-Meier estimate of DoR and DoRC in group B patients with (A) iNHL and (B) aNHL, aggressive B-cell non-Hodgkin lymphoma; DoR, duration of response; DoRC, DoR in complete responders; iNHL, indolent B-cell non-Hodgkin lymphoma; NE, not estimable.

assessment, which precludes a direct comparison with results from studies using the Lugano 2014 criteria.

Mosunetuzumab represents an accessible and readily available off-the-shelf T-cell-engaging therapy option. The excellent tolerability of mosunetuzumab provides a strong rationale for further investigation in combination with other antilymphoma agents. Phase III studies, including SUNMO (ClinicalTrials.gov identifier: [NCT05171647](https://clinicaltrials.gov/ct2/show/study/NCT05171647)) in patients with aNHL and CELESTIMO (ClinicalTrials.gov identifier: [NCT04712097](https://clinicaltrials.gov/ct2/show/study/NCT04712097)) in patients with iNHL, will inform the potential use of mosunetuzumab in

earlier lines of therapy and the optimal sequencing of treatment with other therapeutic agents.

In conclusion, in this extended analysis, fixed-duration mosunetuzumab treatment induced durable responses in heavily pretreated patients with R/R iNHL and aNHL. Patients who achieved CR had durable responses. Importantly, no new safety concerns nor delayed toxicities were identified. Furthermore, mosunetuzumab was efficacious when used for retreatment in cases of disease relapse, confirming its activity across multiple lines of therapy.

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## CLINICAL TRIAL INFORMATION

[NCT02500407](https://clinicaltrials.gov/ct2/show/study/NCT02500407)

## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at DOI <https://doi.org/10.1200/JCO.23.02329>.

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## DATA SHARING STATEMENT

Qualified researchers may request access to individual patient-level data through the clinical study data request platform (<https://vivli.org/>). Further details on Roche's criteria for eligible studies are available at <https://vivli.org/members/ourmembers/>. For further details on Roche's Global Policy on the Sharing of Clinical Information and how to request access to related clinical study documents, see [https://www.roche.com/research\\_and\\_development/who\\_we\\_are\\_how\\_we\\_work/clinical\\_trials/our\\_commitment\\_to\\_data\\_sharing.htm](https://www.roche.com/research_and_development/who_we_are_how_we_work/clinical_trials/our_commitment_to_data_sharing.htm).

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