Data Highlights from ASH 2024

December 12, 2024

Agenda

4:00-4:45 pm (ET)	**Pablo Cagnoni, MD** President, Head of Research & Development	**Introduction / R&D Update**
	Pankit Vachhani, MD The University of Alabama at Birmingham	**BET Inhibitor**
	Laurie Sehn, MD, MPH The University of British Columbia	**Tafasitamab Phase 3 (in*MIND*) study results in follicular lymphoma (FL)**
	Steven Stein, MD Chief Medical Officer	**Additional Development Updates / Closing Remarks**
4:45-5:00 pm (ET)	**Q&A**	

Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this presentation contain predictions, estimates and other forward-looking statements, including any discussion of the following: opportunities for near-term and future product and portfolio growth; the potential and progress of our pipeline and our ability to provide new treatment options for patients, including expectations for our BET inhibitor (INCB057643) and tafasitamab; ongoing development plans, clinical trials and clinical trials to be initiated; expectations regarding data flow, milestones and readouts; expectations regarding regulatory filings, potential regulatory approvals and potential product launches; opportunities for market penetration by our products; and expectations regarding 2024 and future newsflow items.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: future research and development, including the possibility that clinical trials will be unsuccessful or otherwise fail to meet applicable regulatory standards and/or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials, including the ability to enroll subjects in accordance with planned schedules; determinations made by FDA and other regulatory agencies; Incyte's relationships with its collaboration partners; the efficacy or safety of Incyte's products; the acceptance of Incyte's products in the marketplace; market competition; variations in demand for Incyte's products; price regulation or limitations on reimbursement/coverage for Incyte's products; sales, marketing, manufacturing and distribution requirements, including Incyte's ability to successfully commercialize and build commercial infrastructure for newly approved products; unplanned expenses, including expenses relating to litigation or strategic activities; variations in foreign currency exchange rates; and other risks detailed in Incyte's reports filed with the Securities and Exchange Commission, including its annual report on form 10-K and the 10-Q filed for the quarter ending on September 30, 2024. Incyte disclaims any intent or obligation to update these forward-looking statements.

Introduction and R&D Update

Pablo Cagnoni
President, Head of Research & Development

Near-Term Growth Opportunities and Differentiated Pipeline

First-in-Class and/or Best-in-Class Potential

Near-Term Launches and Filings

Axatilimab (anti-CSF1R):

- **Approved** in 3L+ cGVHD in **3Q'24**
- Launch anticipated in **1Q'25**

Ruxolitinib Cream:

- sNDA in pediatric atopic dermatitis (≥2 to <12 yrs) filed **4Q'24**
- Potential **approval** in **2H'25**

Retifanlimab:

- sBLA filing in SCAC by **year-end 2024**
- Potential **approval** in **2H'25**

Tafasitamab:

- sBLA filing in FL by **year-end 2024**
- Potential **approval** in **2H'25**

IAI / Dermatology

Povorcitinib (JAK1i):

- Pivotal trial data in hidradenitis suppurative (HS) anticipated **1H'25**
- PoC data in CSU and asthma anticipated in **1H'25** and **2H'25**, respectively

Ruxolitinib Cream:

- Phase 3 trial in mild-moderate HS to initiate in **1H'25**
- Phase 3 data in prurigo nodularis anticipated in **1H'25**

Anti-CD122 (IL-15Rβ):

- Phase 1 data anticipated in **2025**

Oncology

Tafasitamab:

- Phase 3 data in 1L DLBCL in **1H'25**

CDK2i:

- Phase 3 trial(s) in ovarian cancer to initiate in **2025**

TGFβR2 x PD-1:

- Clinical proof-of-concept data anticipated in **2025**

KRASG12Di:

- Clinical proof-of-concept data anticipated in **2025**

MPN/GVHD

Ruxolitinib XR (QD):

- Pivotal data from BE study anticipated in **1H'25**

BETi:

- Phase 3 initiation in MF anticipated in **2025**

mCALR:

- Clinical proof-of-concept data anticipated in **2025**

JAK2V617Fi:

- Clinical proof-of-concept data anticipated in **2025**

cGVHD= chronic Graft versus Host Disease; FL= follicular lymphoma; DLBCL= diffuse large B-cell lymphoma; SCAC= squamous cell anal carcinoma; HS= hidradenitis suppurativa; BE= bioequivalence; MF= myelofibrosis

ALK2 Program Update

ALK2 inhibition reduced hepcidin levels but did not improve anemia in MF patients

Hypothesis: Zilurgisertib (INCB000928) binding to ALK2 should block its downstream signaling events to:

- Downregulate hepcidin expression
- Relieve the functional iron deficiency caused by elevated hepcidin by restoring ferroportin
- Mobilize iron for erythropoiesis
- Improve anemia due to inflammation in MF and other hematologic malignancies

Study 104 MF Summary

Main study endpoint: Anemia response

Open Label, Dose Escalation + Dose Expansion

TGA: -928 Monotherapy
TD or symptomatic anaemia due to MF resistant, refractory, lost response to or intolerant/ineligible for JAKi

TGB: -928 Add on to Rux
TD or symptomatic anemia due to MF
Stable dose of ruxolitinib ≥12 weeks

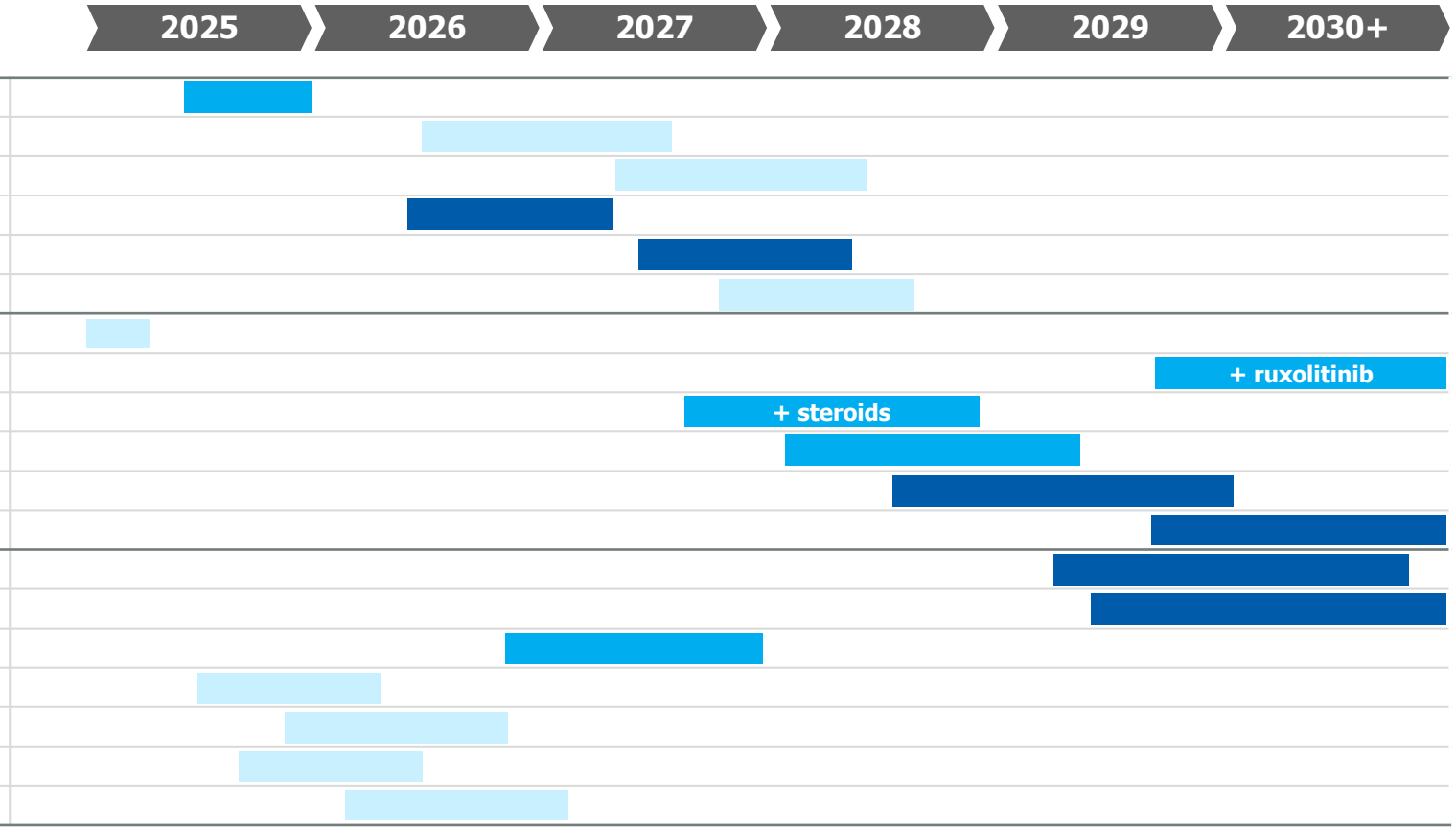
TGC: -928 + Rux in Naïve pts
TD or symptomatic anemia due to MF
No prior treatment by any JAKi treatment

Doses explored reach desired target **exposure**?	🟢
Evidence of **target engagement**: Hepcidin reduction?	🟢
Hepcidin reduction reach normal levels & is sustained over time?	🟡
PD: Serum Iron increased in NTD responders as expected by MoA?	🔴
PD: Hepcidin and Ferritin decreased in NTD responders as expected by MoA?	🔴
Correlation between Hepcidin changes and Hgb improvements in NTD patients?	🔴
Correlation between exposure and response?	🔴

TGA= treatment group A; TGB= treatment group B; TGC= treatment group C

>10 Potential High Impact Launches by 2030

	Product	Indication	Status
Derm/IAI †	Ruxolitinib Cream	Pediatric AD	sNDA
		Prurigo Nodularis	Phase 3
		HS (mild/mod)	Phase 3
	Povorcitinib	HS (mod/sev)	Phase 3
		Vitiligo	Phase 3
		Prurigo Nodularis	Phase 3
MPN/GVHD	Axatilimab	3L cGVHD	Approved
		1L cGVHD	Phase 2
		1L cGVHD	Phase 3
	BETi	MF	Phase 3*
	mCALR	MF & ET	Phase 1
	JAK2V617Fi	MF, PV & ET	Phase 1
Oncology	KRASG12D	Solid Tumors	Phase 1
	TGFßR2×PD-1	Solid Tumors	Phase 1
	CDK2i	Solid Tumors	Phase 3*
	Retifanlimab	SCAC	Phase 3
		NSCLC	Phase 3
	Tafasitamab	FL	Phase 3
		1L DLBCL	Phase 3



* In planning

Potential U.S. approval/launch range and U.S **addressable market size** < $1B $1-3B > $3B

† MRGPRX2 removed due to paused enrollment

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INCB057643 (BET Inhibitor)

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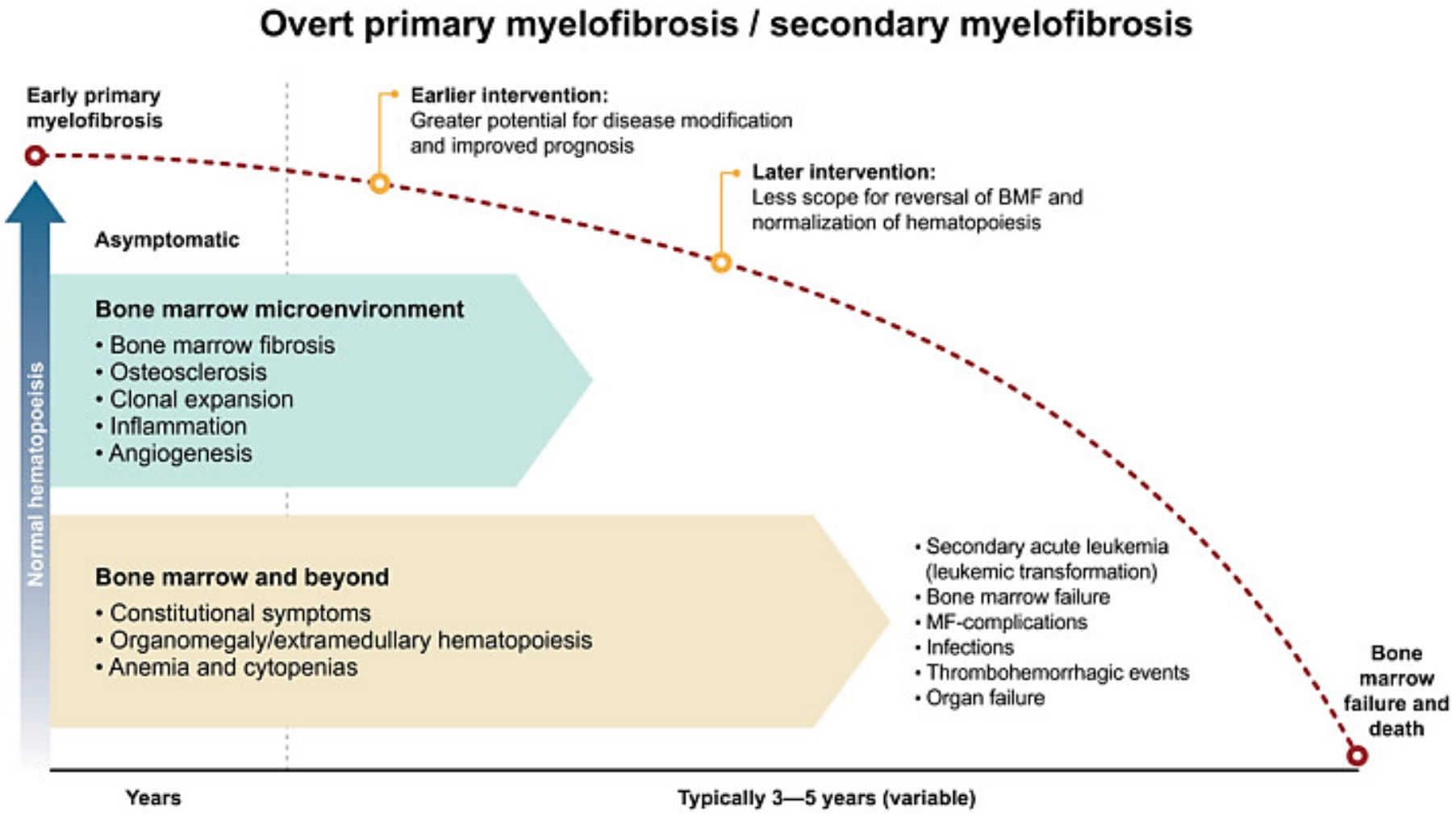
MF: Natural History and Time Points for Intervention



Pemmaraju N, et al. Cancer. 2022

MF Current Landscape: JAK Inhibitors

		Ruxolitinib	Fedratinib	Pacritinib	Momelotinib
Target		JAK1 and JAK2	JAK2, JAK1 (weak), FLT3	JAK2, FLT3, IRAK1, CSF1R, and ACVR1	JAK1, JAK2, and ACVR1
Indication	Population	Intermediate or high-risk MF	Intermediate-2 or high-risk MF	Intermediate or high-risk MF with platelet count $<50\times10^9$/L	Intermediate or high-risk MF with anemia
	Approved Line	Line agnostic	Line agnostic	Line agnostic	Line agnostic
Notable AEs		Cytopenias (anemia, thrombocytopenia), infection, weight gain	Wernicke encephalopathy, GI toxicity	Hemorrhage, cardiovascular events, GI (diarrhea, nausea)	Cytopenias (anemia, thrombocytopenia)

Pros

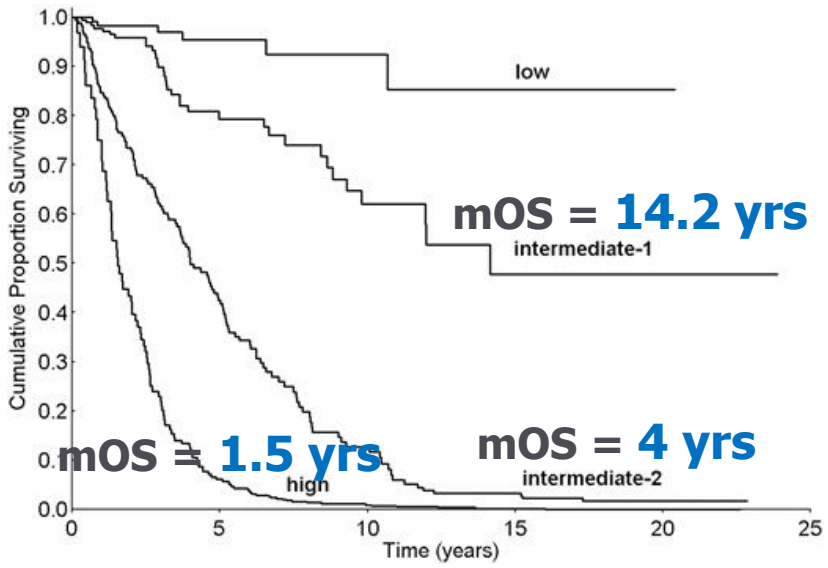
- All improve spleen volumes/sizes
- All improve symptoms as compared to placebo/BAT
- Improve OS (data mostly with ruxolitinib)
- Some improve anemia

Cons

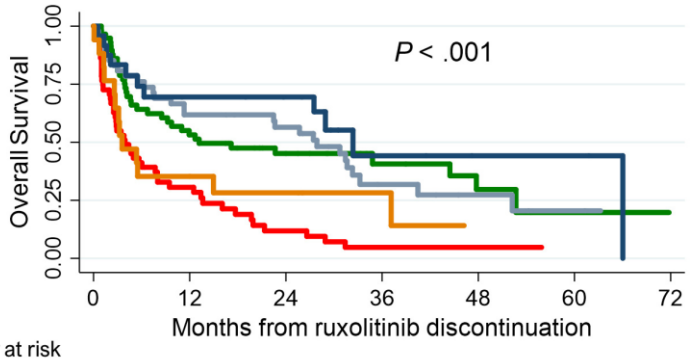
- Do not alter the natural progression of the disease
- No consistent or durable improvement in fibrosis
- No major impact on mutated gene burden
- No impact on leukemic transformation

Myelofibrosis: An Overview

OS based on DIPSS risk stratification in PMF



OS after rux discontinuation



Number at risk							
Blast phase	51	14	5	1	1	0	0
RUX-related AE	60	29	19	9	5	1	0
Lack of response	50	26	21	7	4	2	0
Loss of response	26	14	12	4	2	2	0
RUX-unrelated AE	20	6	4	2	0	0	0

mOS (overall cohort) = **13.2 mos**

Other studies with similar results of OS = 12-18 months post rux

Unmet needs in MF

- More, deeper, and sustained spleen and symptom responses
- Achieve “disease modification” benefits
- Management of cytopenic MF – especially anemia
- Improve survival outcomes:
  - beyond that from ruxolitnib in 1L
  - 2L+ (i.e. post JAKi failure)
  - AP/BP MF
- Drugs with MOA beyond JAKi
  - target pathways beyond JAK/STAT pathway

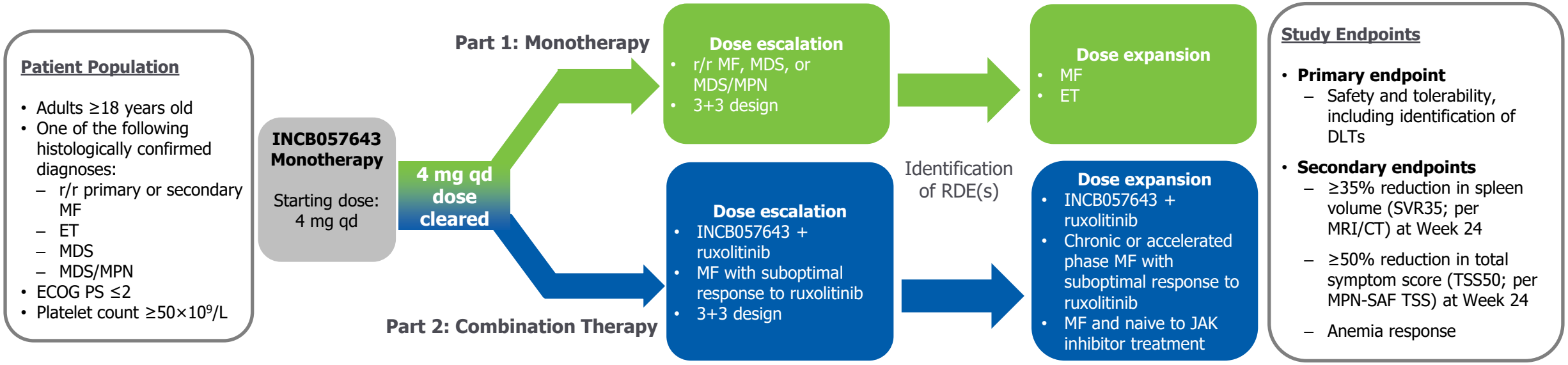
Passamonti F, et al. Blood. 2010; Palandri F, et al. Cancer 2019;

Safety and Efficacy of Bromodomain and Extra-Terminal Inhibitor INCB057643 in Patients With Relapsed or Refractory Myelofibrosis and Other Advanced Myeloid Neoplasms: A Phase 1 Study

Study Design

Ongoing Open-Label, Phase 1, Dose-Escalation and Expansion Study (NCT04279847)

- The initial INCB057643 dose was 4 mg qd with dose escalation up to 12 mg qd
  - All doses were administered continuously in 28-day cycles



- Anemia response
  - If transfusion-independent at baseline: ≥1.5 g/dL hemoglobin increase from baseline for ≥12 weeks
  - If transfusion-dependent at baseline: achieving transfusion independence for ≥12 weeks

DLT= dose-limiting toxicity; ECOG PS= Eastern Cooperative Oncology Group performance status; RDE= recommended dose for expansion; SAF TSS= Symptom Assessment Form total symptom score; SVR35= ≥35% reduction from baseline in spleen volume; TSS50= ≥50% reduction from baseline in MPN-SAF TSS

Patient Demographics and Baseline Characteristics

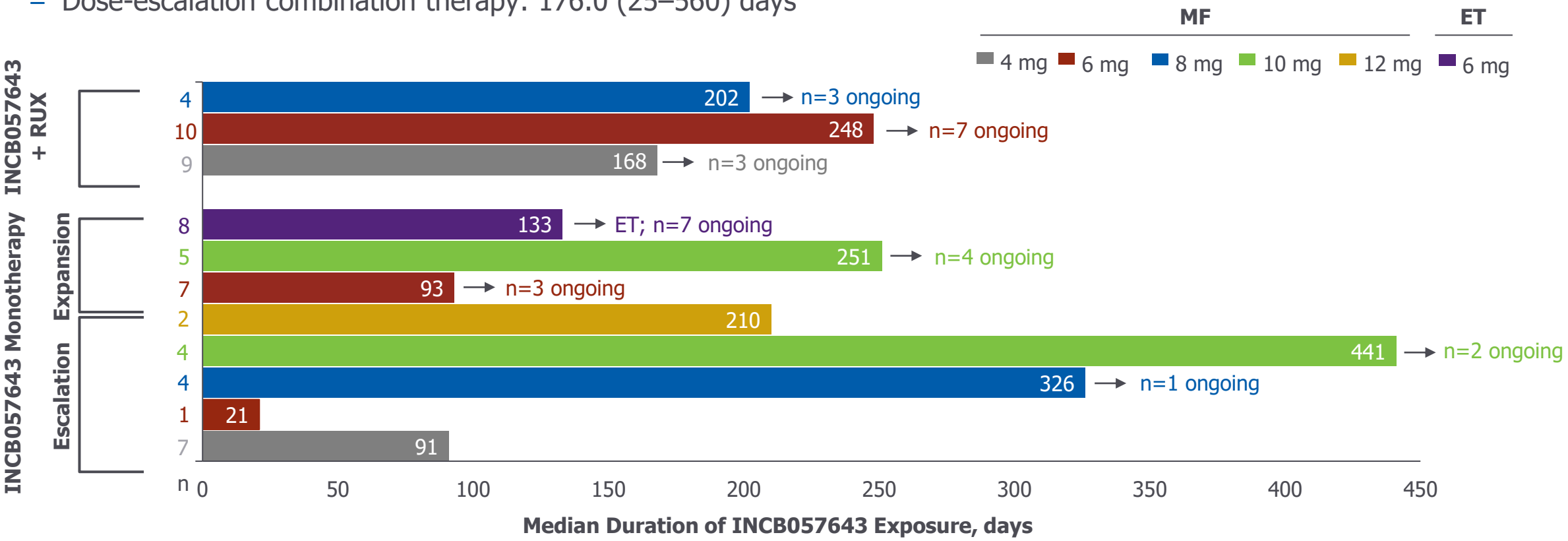
Parameter	Part 1 (INCB057643 Monotherapy)				Part 2 (INCB057643 + RUX)
	Dose Escalation (n=18)		Dose Expansion (n=20)		Dose Escalation (n=23)
	MF (n=13)	MDS and MDS/MPN* (n=5)	MF (n=12)	ET (n=8)	MF
Age, median (range), y	71.0 (50.0–79.0)		66.5 (47.0–79.0)		70.0 (50.0–77.0)
Male, n (%)	11 (61.1)		11 (55.0)		14 (60.9)
White, n (%)	14 (77.8)		12 (60.0)		19 (82.6)
Time since initial diagnosis, median (range), y	4.7 (1.8–13.4)	2.0 (0.8–8.2)	5.6 (1.2–17.5)	3.8 (1.2–16.2)	4.1 (0.02–12.9)
RBC transfusion dependent, %	15.4	20.0	16.7	0	8.7
PMF/PPV-MF/PET-MF, %	38.5 / 30.8 / 30.8	NA	50.0 / 33.3 / 16.7	NA	56.5 / 26.1 / 17.4
IWG risk level high/int-2, %	15.4 / 84.6	NA	33.3 / 66.7	NA	8.7 / 78.3
JAK2-positive, %	61.5	NA	50.0	NA	73.9
CALR exon 9 mutation-positive, %	NA	NA	NA	12.5	NA
Spleen volume, median (range), cm^3	2028 (618–4766)	NA	2741.5 (625–4047)	NA	1940 (634–4381)
Spleen length, median (range), cm	11.0 (3–24)	NA	13.0 (5–25)	NA	12.0 (6–25)
TSS, mean (range)	35.5 (22.0–47.0)	NA	36.2 (0–77)	NA	20.3 (0–57.0)

CMML= chronic myelomonocytic leukemia; int= intermediate; IWG= International Working Group; PET-MF= post–essential thrombocythemia myelofibrosis; PMF= primary myelofibrosis; PPV-MF= post–polycythemia vera myelofibrosis; RBC= red blood cell; RS-T= ring sideroblasts and thrombocytosis.
* MDS, n=2; CMML, n=1; MDS/MPN-RS-T; n=1; unclassified overlap syndrome, n=1.

Treatment Duration

Data Cutoff: September 9, 2024

- Median (range) duration of INCB057643 exposure
  - Dose-escalation monotherapy: 195.5 (15–812) days
  - Dose-expansion monotherapy: 154.5 (14–341) days
  - Dose-escalation combination therapy: 176.0 (25–560) days



Safety

- There were 2 DLTs with monotherapy:
  - Hyperbilirubinemia
    - Patient with MF, 12-mg cohort
  - Thrombocytopenia
    - Patient with MDS/MPN, 12-mg cohort
- There was 1 DLT with combination therapy:
  - Thrombocytopenia
    - Patient with MF, 6-mg cohort
- There were 3 cases of AML transformation
  - 1 MDS/MPN (4 mg mono), 1 MDS (10 mg mono)
  - 1 MF (4 mg combo with ruxolitinib 20 mg bid)

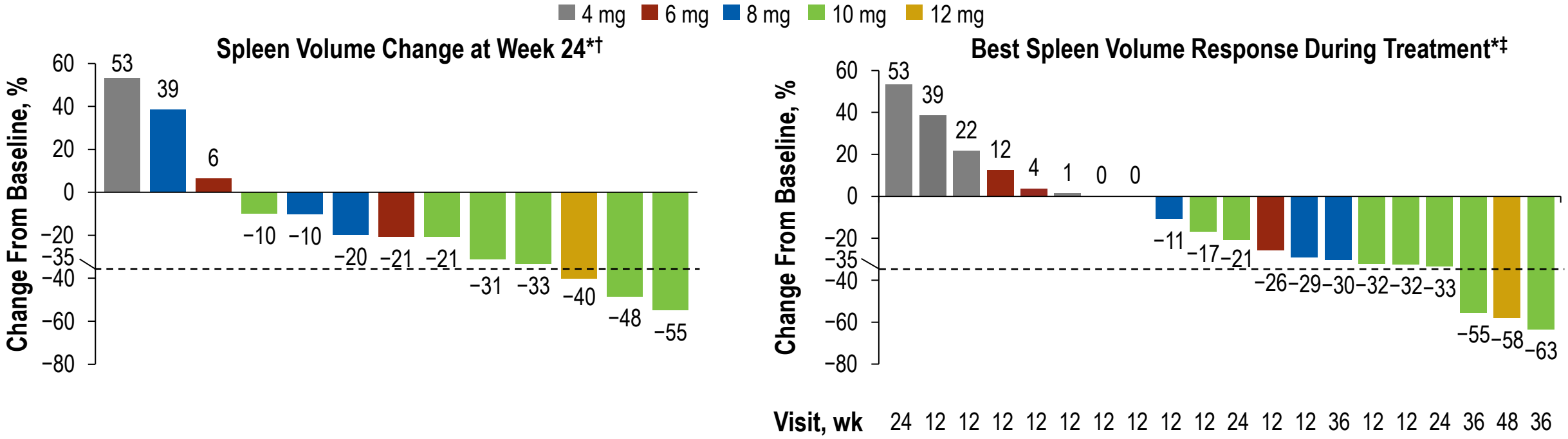
	Part 1 (INCB057643 Monotherapy)		Part 2 (INCB057643 + RUX)	
Parameter, n (%)	**Dose Escalation (n=18)**	**Dose Expansion (n=20)**	**Dose Escalation (n=23)**	**Total (N=61)**
Any TEAE	18 (100)	18 (90.0)	22 (95.7)	58 (95.1)
Grade ≥3 TEAE*	16 (88.9)	8 (40.0)	11 (47.8)	35 (57.4)
TEAE leading to discontinuation†	5 (27.8)	2 (10.0)	2 (8.7)	9 (14.8)
Serious TEAE	8 (44.4)	6 (30.0)	5 (21.7)	19 (31.1)
Fatal TEAE‡	1 (5.6)	0	2 (8.7)	3 (4.9)
Treatment-related TEAE	17 (94.4)	15 (75.0)	16 (69.6)	48 (78.7)
Treatment-related serious TEAE§	1 (5.6)	1 (5.0)	1 (4.3)	3 (4.9)
Treatment-related fatal TEAE	0	0	0	0
Most common TEAEs,¶ n (%)				
Thrombocytopenia‖	11 (61.1)	5 (25.0)	12 (52.2)	28 (45.9)
Anemia	7 (38.9)	2 (10.0)	6 (26.1)	15 (24.6)
Nausea	9 (50.0)	2 (10.0)	2 (8.7)	13 (21.3)
Blood bilirubin increased	7 (38.9)	2 (10.0)	2 (8.7)	11 (18.0)
Dysgeusia	5 (27.8)	4 (20.0)	2 (8.7)	11 (18.0)
Pruritus	6 (33.3)	0	2 (8.7)	8 (13.1)

TEAE= treatment-emergent adverse event.
* Grade ≥3 TEAEs occurring in >3 patients: anemia (n=12), thrombocytopenia‖ (n=16). † TEAEs leading to discontinuation of INCB057643: thrombocytopenia‖ (n=5), acute myeloid leukemia (n=1), anemia (n=1), bacteremia (n=1), ejection fraction decreased (n=1), skin lesion (n=1). ‡ Fatal TEAEs: AML (acute myeloid leukemia; n=2), cardiac arrest (n=1). § Treatment-related serious TEAEs: hematoma (n=1), herpes zoster (n=1), pneumonia (n=1). ¶ TEAEs occurring in ≥10% of patients in the total population. ‖ Includes thrombocytopenia and platelet count decreased.

Efficacy – Monotherapy

Spleen Volume Response in Individual Patients With MF (n=25)

- Week 24 SVR35 achieved by 3/7 patients receiving INCB057643 ≥10 mg and 3/20 all evaluable patients
- Of 23 evaluable patients, BOR SVR35 achieved by 3 patients; SVR25 achieved by 9 patients



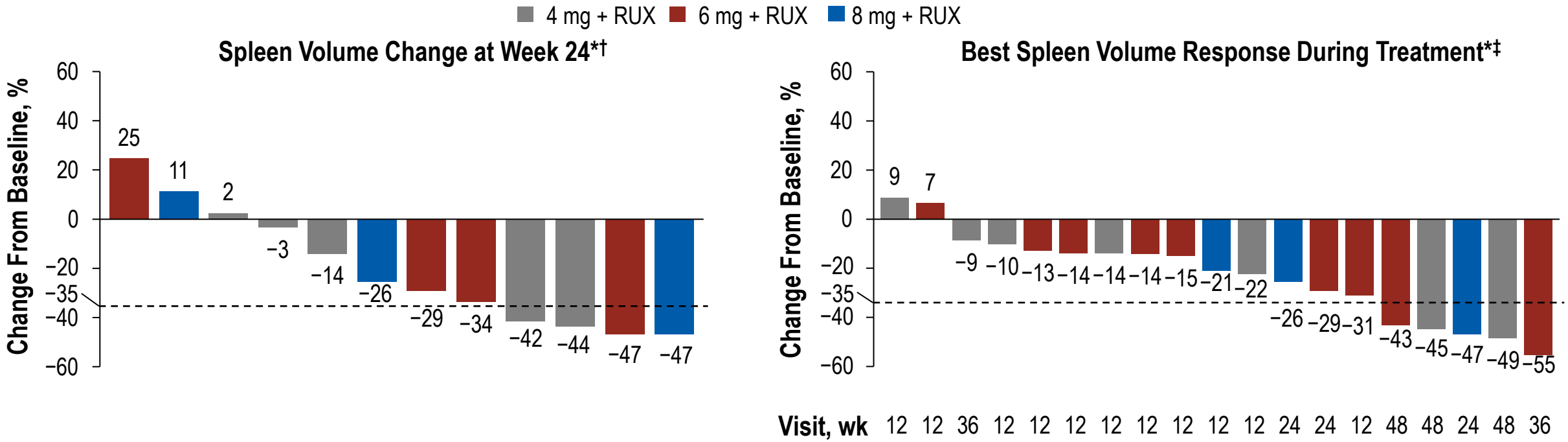
BOR= best overall response.

* Dotted line represents response criteria threshold. † 7 evaluable patients (4 mg, n=4; 6 mg, n=3) discontinued treatment before Week 24; 5 patients were ongoing (6 mg, n=3; 10 mg, n=2) and not evaluable because they were not followed up long enough and had no Week 24 assessment. ‡ 3 evaluable patients (6 mg n=2; 10 mg n=1) discontinued treatment before first postbaseline (Week 12) spleen volume assessment or missed the assessment; 2 patients (6 mg) were not evaluable because they were not followed up long enough to reach the first postbaseline spleen volume assessment.

Efficacy – Combination Therapy ("Add-on")

Spleen Volume Response in Individual Patients With MF With Suboptimal RUX Response (n=23)

- Week 24 SVR35 achieved by 4/17 evaluable patients
- BOR SVR35 achieved by 5/20 evaluable patients; BOR SVR25 achieved by 8 patients

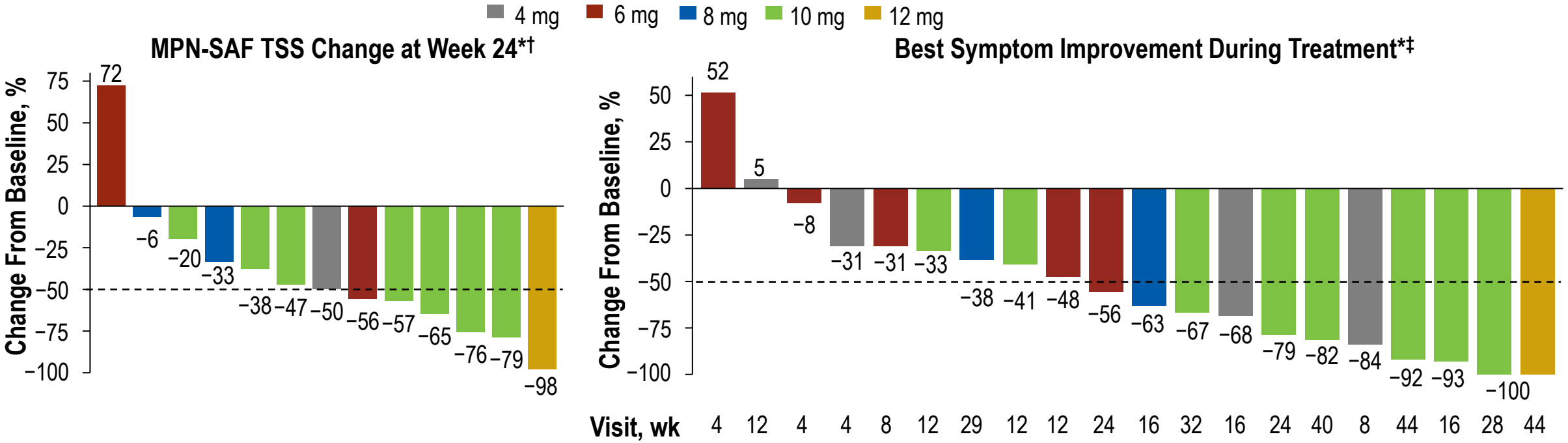


* Dotted line represents response criteria threshold. † 4 evaluable patients (4 mg + RUX, n=3; 6 mg + RUX, n=1) discontinued treatment before Week 24; 1 evaluable patient (6 mg + RUX) was missing Week 24 data; 6 patients were ongoing (4 mg + RUX, n=1; 6 mg + RUX, n=4; 8 mg + RUX, n=1) and not evaluable because they were not followed up long enough and had no Week 24 assessment. ‡ 1 evaluable patient (4 mg) was missing Week 12 data; 3 patients (4 mg, 6 mg, and 8 mg, n=1 each) were not evaluable because they were not followed up long enough to reach the first postbaseline spleen volume assessment.

Efficacy – Monotherapy

Symptom Response in Individual Patients With MF (n=25)

- Week 24 TSS50 achieved by 5/8 evaluable patients receiving INCB057643 ≥10 mg; 7/19 all evaluable patients
- BOR TSS50 achieved by 11/20 evaluable patients

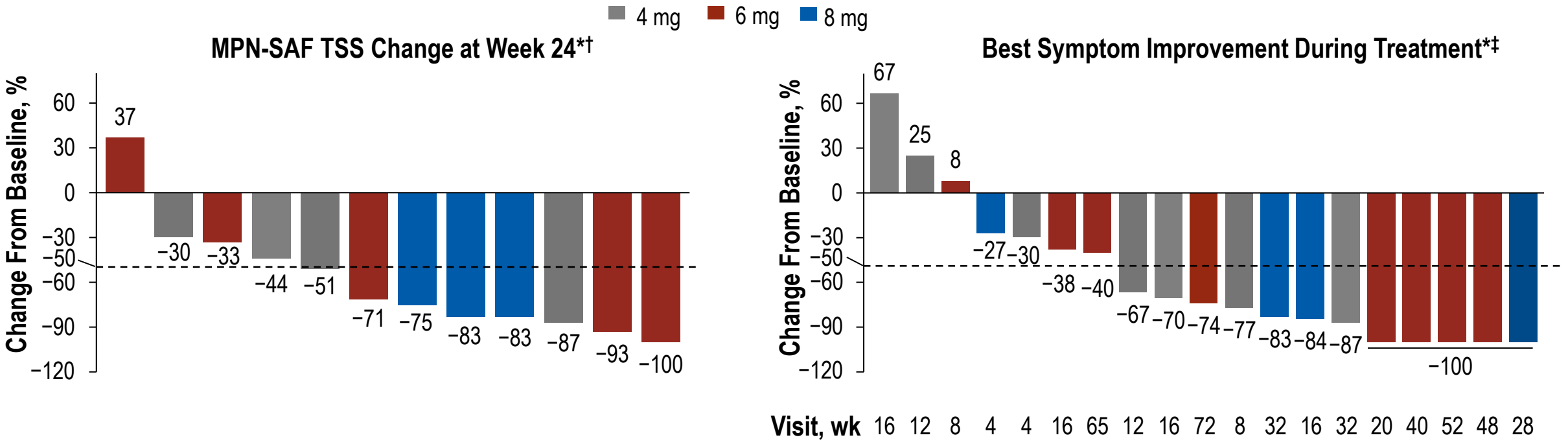


* Dotted line represents response criteria threshold. † 6 evaluable patients (4 mg, n=3; 6 mg, n=3) discontinued treatment before Week 24; 6 patients were not evaluable: 1 (4 mg) was missing baseline data, 4 were ongoing (6 mg, n=3; 10 mg, n=1) but not followed up long enough and had no Week 24 assessment, 1 of which (6 mg) and 1 additional (8 mg) had baseline TSS <5. ‡ 5 patients not evaluable: 2 were ongoing but not followed long enough (6 mg), 2 had baseline TSS <5 (6 mg and 8 mg, n=1 each), and 1 did not have baseline data (4 mg).

Efficacy – Combination Therapy ("Add-on")

Symptom Response in Individual Patients With MF With Suboptimal RUX Response (n=23)

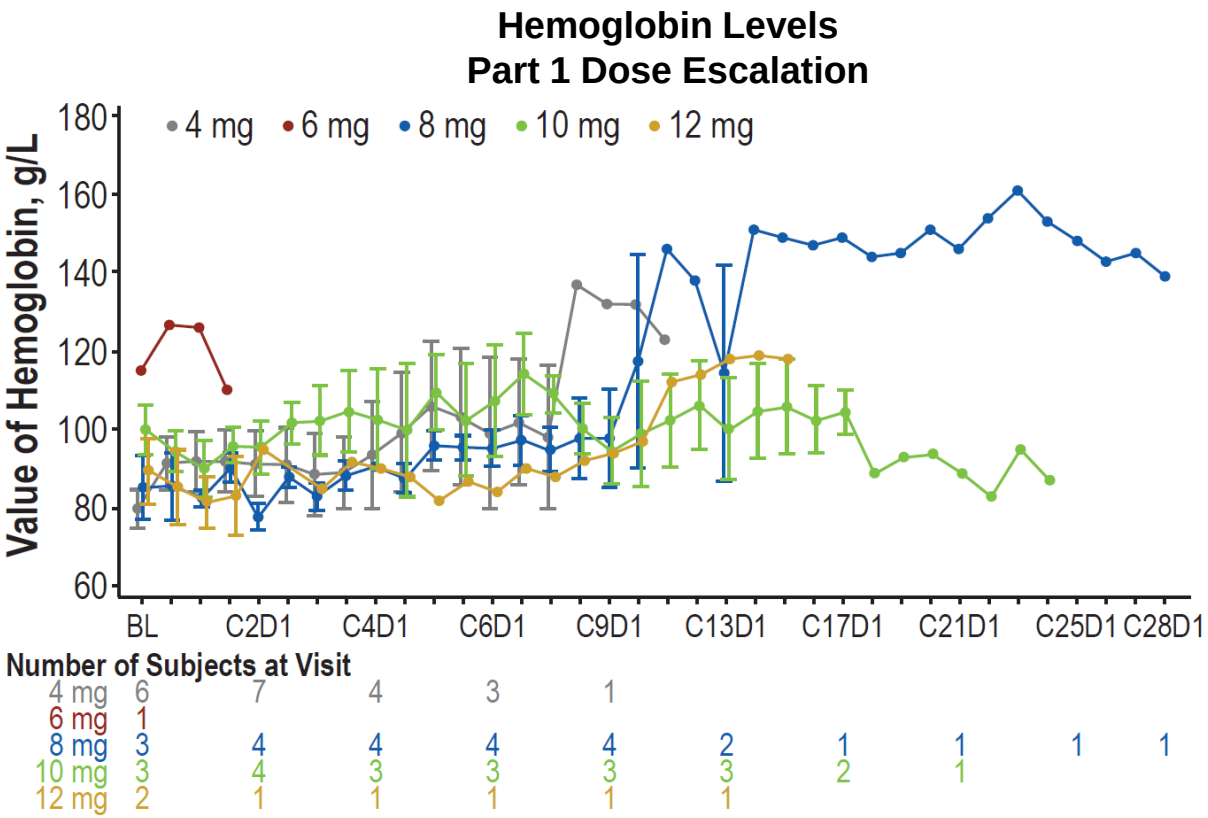
- At Week 24, TSS50 was achieved by 8/16 evaluable patients
- BOR TSS50 achieved by 12/19 evaluable patients

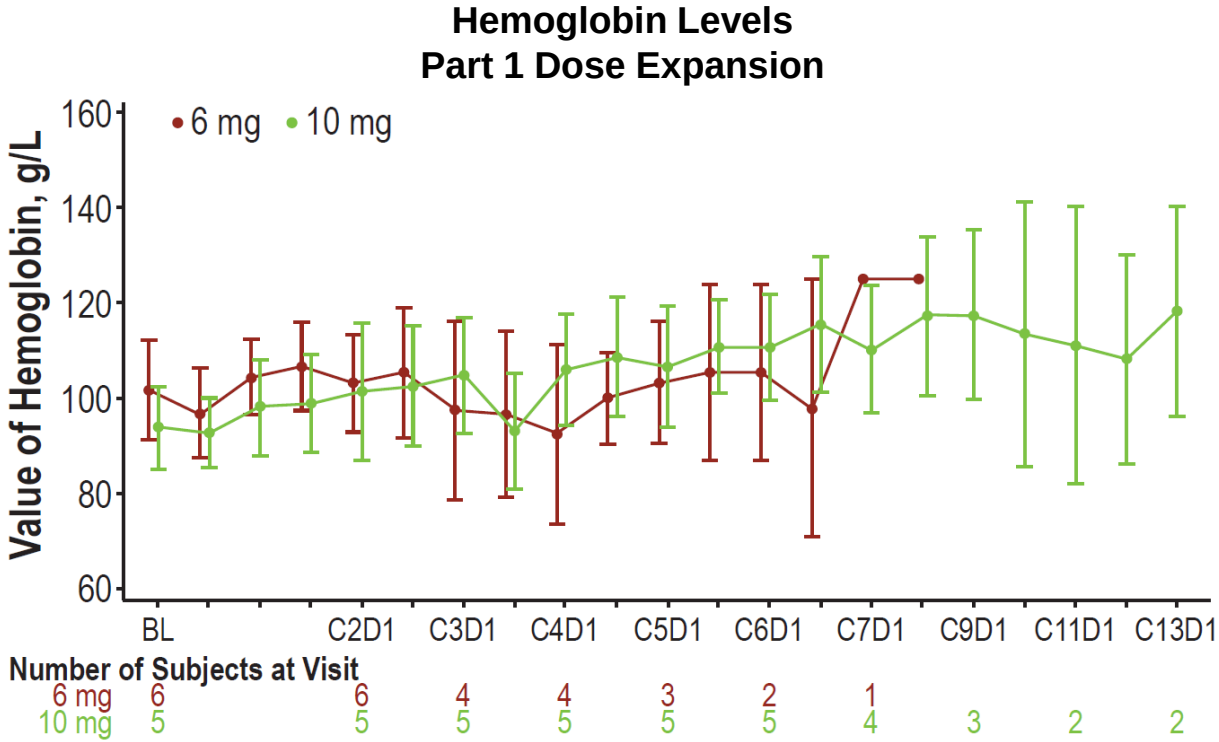


* Dotted line represents response criteria threshold. † 4 evaluable patients (4 mg + RUX, n=3; 6 mg + RUX, n=1) discontinued treatment before Week 24; 7 patients were not evaluable, 6 were ongoing but not followed up long enough (4 mg + RUX, n=1; 6 mg + RUX, n=4; 8 mg + RUX, n=1), 2 had baseline TSS <5 (4 mg + RUX and 6 mg + RUX, n=1 each). ‡ 4 patients were not evaluable, 2 were ongoing but did not have postbaseline data (4 mg + RUX and 6 mg + RUX, n=1 each), 2 had baseline TSS <5 (4 mg + RUX and 6 mg + RUX, n=1 each).

Hemoglobin Levels - Monotherapy

- 6/22 (27%) evaluable patients achieved anemia response,* including 4/18 baseline transfusion-independent and 2/4 baseline transfusion-dependent patients



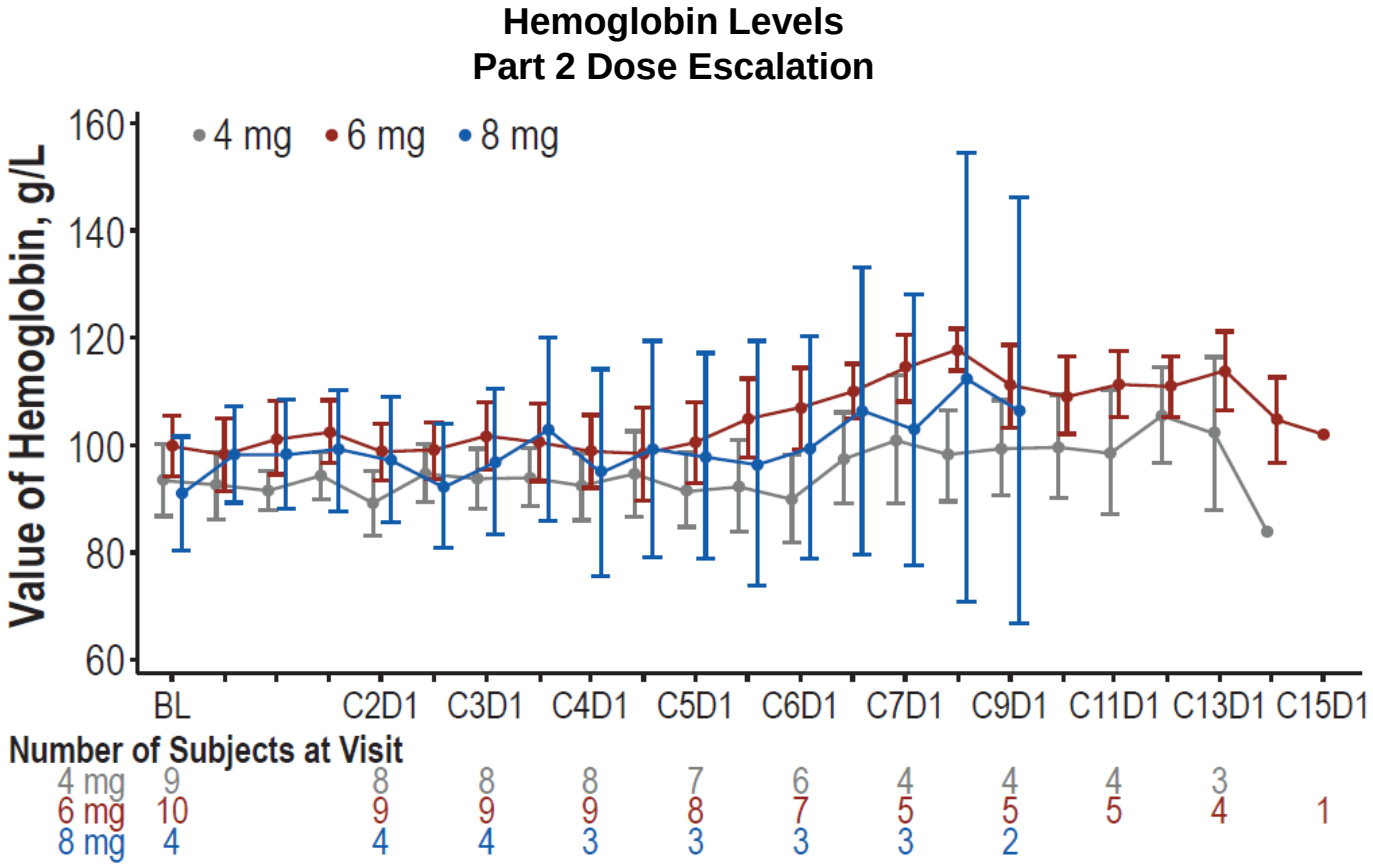


BL= baseline; C= cycle; D= day.
* An anemia response was defined as >1.5 g/dL hemoglobin increase from baseline for transfusion-independent patients at baseline, and achieving transfusion independence for transfusion-dependent patients.

Hemoglobin Levels – Combination Therapy ("Add-on")

Patients With MF With Suboptimal RUX Response

- 4/20 (20%) evaluable patients achieved anemia response*



* An anemia response was defined as >1.5 g/dL hemoglobin increase from baseline for transfusion-independent patients at baseline, and achieving transfusion independence for transfusion-dependent patients. Analysis included 4/18 baseline transfusion-independent and 0/2 baseline transfusion-dependent patients.

Conclusions

- Treatment with INCB057643 monotherapy or in combination with ruxolitinib was generally well tolerated
  - 2 DLTs occurred with INCB057643 monotherapy (12 mg: thrombocytopenia, hyperbilirubinemia)
  - 1 DLT occurred with INCB057643 6-mg combination therapy (thrombocytopenia)
  - There were few treatment-related serious TEAEs and no treatment-related fatal events
  - The most common TEAEs were thrombocytopenia, anemia, nausea, blood bilirubin increased, and dysgeusia
- Improvements in anemia, spleen size, and symptom burden were observed in patients receiving INCB057643 monotherapy and in combination with ruxolitinib
- Dose expansion is ongoing for 6-mg and 10-mg INCB057643 monotherapy
  - 12 patients with MF and 8 with ET have been enrolled in the part 1 expansion phase
- Dose expansion is ongoing for the 4-mg and 8-mg combination ("add-on") therapy groups
- Enrollment is ongoing for the JAK inhibitor–naive combination therapy group

Follicular Lymphoma (FL)

Laurie Sehn, MD, MPH

Clinical Professor of Medicine – Medical Oncology
BC Cancer Centre for Lymphoid Cancer
The University of British Columbia

Background

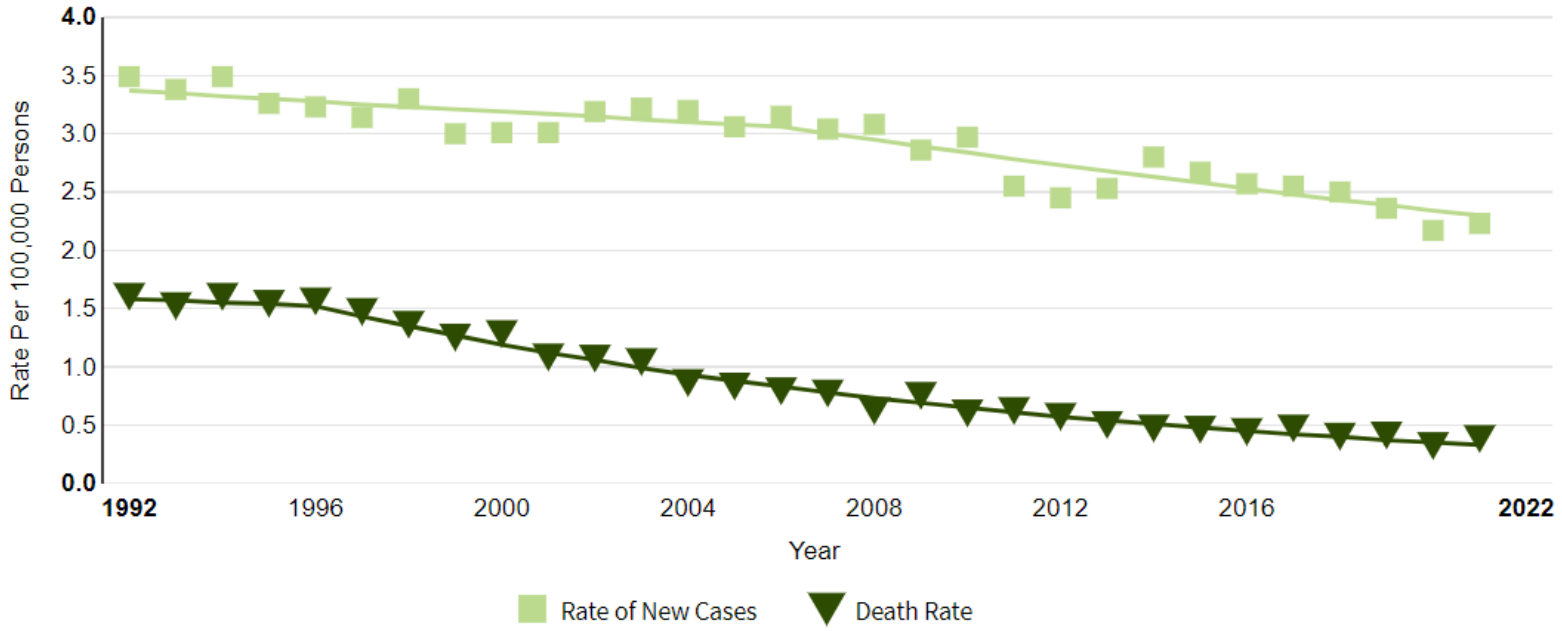
- Follicular lymphoma (FL) is an indolent NHL sub-type which represents ~15-20% of NHL
  - Most common form of indolent lymphoma
- Most patients with FL experience relapsed or refractory disease (R/R) and need multiple lines of therapy
  - Refractory patients or those who progress < 24 months since last treatment, generally have poorer outcomes and represent an area of high unmet need
  - Chemoimmunotherapy is often used frontline but yields shorter remissions with each treatment
  - Immunotherapy options are now preferred in the R/R setting, but improved durability is needed
- Lenalidomide (len) + rituximab (R) is approved for R/R FL based on the AUGMENT study[1]
- Tafasitamab, a CD19-targeted mAb, induces direct cytotoxicity and enhances NK cell and macrophage immune-mediated mechanisms
  - Tafasitamab + len is approved for patients with transplant-ineligible R/R DLBCL based on the L-MIND study[2]

1. Leonard JP, et al. *J Clin Oncol.* 2019;37:1188-1899. 2. Salles G, et al. *Lancet Oncol.* 2020;21:978-988.
DLBCL= diffuse large B-cell lymphoma; FL= follicular lymphoma; mAb= monoclonal antibody; NK= natural killer; NHL= non-Hodgkin's lymphoma

Epidemiology of Follicular Lymphoma (U.S)

Rates of New FL Cases and Associated Mortality[1]

NCI Seer data based on the US population



The rate of new cases of follicular lymphoma was 2.5 per 100,000 people per year

The death rate was 0.4 per 100,000 people per year

These rates are age-adjusted and based on 2017–2021 cases and deaths

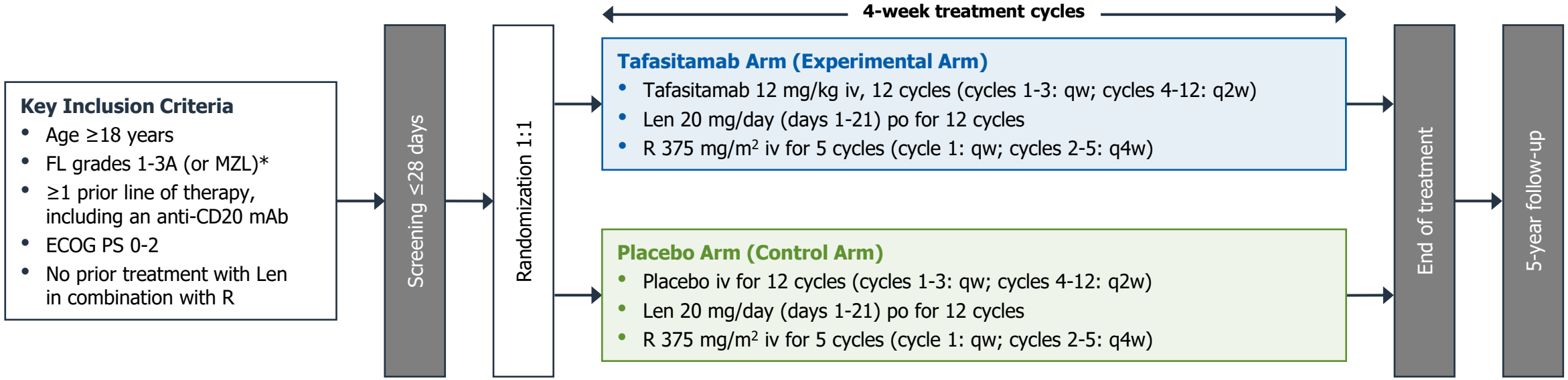
1. National Cancer Institute. Cancer Stat Facts — Follicular Lymphoma (FL). https://seer.cancer.gov/statfacts/html/follicular.html.

The Challenge of Follicular Lymphoma

- Indolent behavior and is responsive to many treatments, but remains incurable
- Most patients have prolonged survival, but a subset have propensity to transformation or treatment-resistance with poor outcomes
- Wide range of treatment options of varying intensity
- Goal is to control disease and maintain quality of life
- Tafasitamab + R^2 has the potential to become the first, novel immunotherapy combination of a CD19 and CD20 antibody

Tafasitamab Plus Lenalidomide and Rituximab for Relapsed or Refractory Follicular Lymphoma: Results From a Phase 3 Study *(inMIND)*

inMIND: Phase 3, Double-Blind, Placebo-Controlled, International, Multicenter Randomized Study



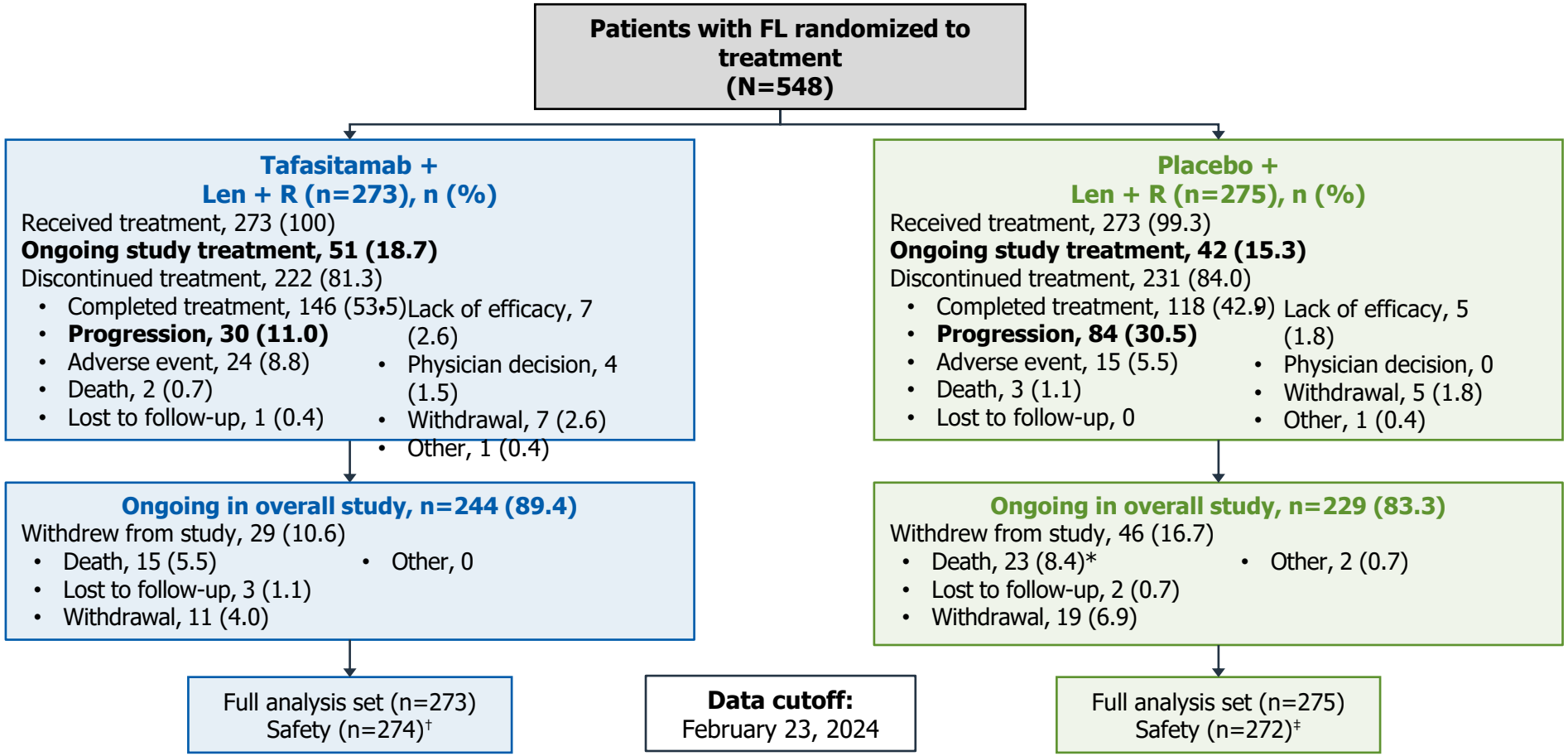
Stratification Factors (Patients With FL)
- POD24
- Refractoriness to prior anti-CD20 mAb therapy
- Number of prior lines of therapy (1 or ≥2)

Study Endpoints in FL Population (Investigator Assessed Unless Specified)
- **Primary study endpoint:** **PFS**
- **Key secondary:** PET-CR rate in the FDG-avid population, OS
- **Select other secondary:** PFS by IRC, ORR, DOR, safety, QoL, MRD
- **Exploratory:** TTNT, B-cell recovery, Ig levels, CD19 expression

- Powered to assess PFS in the FL population, triggered when 174 investigator-assessed events occurred
- OS analysis planned after 5 years of follow-up

*Limited number of patients with MZL were enrolled but the study was not powered for this population; data for patients with MZL will be presented separately. DOR= duration of response; ECOG PS= Eastern Cooperative Oncology Group performance status; FDG= fluorodeoxyglucose; FL= follicular lymphoma; Ig= immunoglobulin; IRC= independent review committee; iv= intravenous; Len= lenalidomide; mAb= monoclonal antibody; MRD= minimal residual disease; MZL= marginal zone lymphoma; ORR= overall response rate; OS= overall survival; PET-CR= positron emission tomography-complete response; PFS= progression-free survival; po= orally; POD24= disease progression within 24 months of initial diagnosis; QoL= quality of life; qw= weekly; q2w= every 2 weeks; q4w= every 4 weeks; R= rituximab; TTNT= time to next treatment

Patient Disposition



- At primary analysis, median number of cycles received was 12 with tafasitamab and 11 with placebo

*Death for 1 patient was reported but not recorded in the end-of-study form. †One patient randomized to the placebo + len + R group is included in the tafasitamab + len + R safety population because the patient erroneously received tafasitamab. ‡Three patients randomized to the placebo + len + R group are not included in the safety population because they erroneously received tafasitamab (n=1), or did not receive any study treatment due to confirmation of R hypersensitivity (n=1), or the patient withdrew from the study (n=1). FL= follicular lymphoma; Len= lenalidomide; R= rituximab

Baseline Characteristics

Variable	Tafasitamab + Len + R (n=273)	Placebo + Len + R (n=275)	Total (N=548)
Median age, years (range)	64.0 (36, 88)	64.0 (31, 85)	64.0 (31, 88)
≥75, n (%)	54 (19.8)	54 (19.6)	108 (19.7)
Male sex, n (%)	150 (54.9)	149 (54.2)	299 (54.6)
Median time since initial diagnosis of FL, years (range)	5.2 (0, 34)	5.5 (1, 33)	5.3 (0, 34)
ECOG PS at screening, n (%)			
0	181 (66.3)	192 (69.8)	373 (68.1)
1-2	92 (33.7)	83 (30.2)	175 (31.9)
Ann Arbor stage, n (%)			
I or II	52 (19.0)	50 (18.2)	102 (18.6)
III or IV	221 (81.0)	225 (81.8)	446 (81.4)
FL grade, n (%)			
1 or 2	203 (74.4)	203 (73.8)	406 (74.1)
3A	67 (24.5)	71 (25.8)	138 (25.2)
B symptoms, n (%)	63 (23.1)	67 (24.4)	130 (23.7)
FLIPI score, n (%)			
0-1	57 (20.9)	57 (20.7)	114 (20.8)
2	79 (28.9)	67 (24.4)	146 (26.6)
3-5	137 (50.2)	150 (54.5)	287 (52.4)
GELF criteria, n (%)	222 (81.3)	232 (84.4)	454 (82.8)
FL diagnosis confirmed by central pathology, n (%)	256 (93.8)	259 (90.5)	505 (92.2)

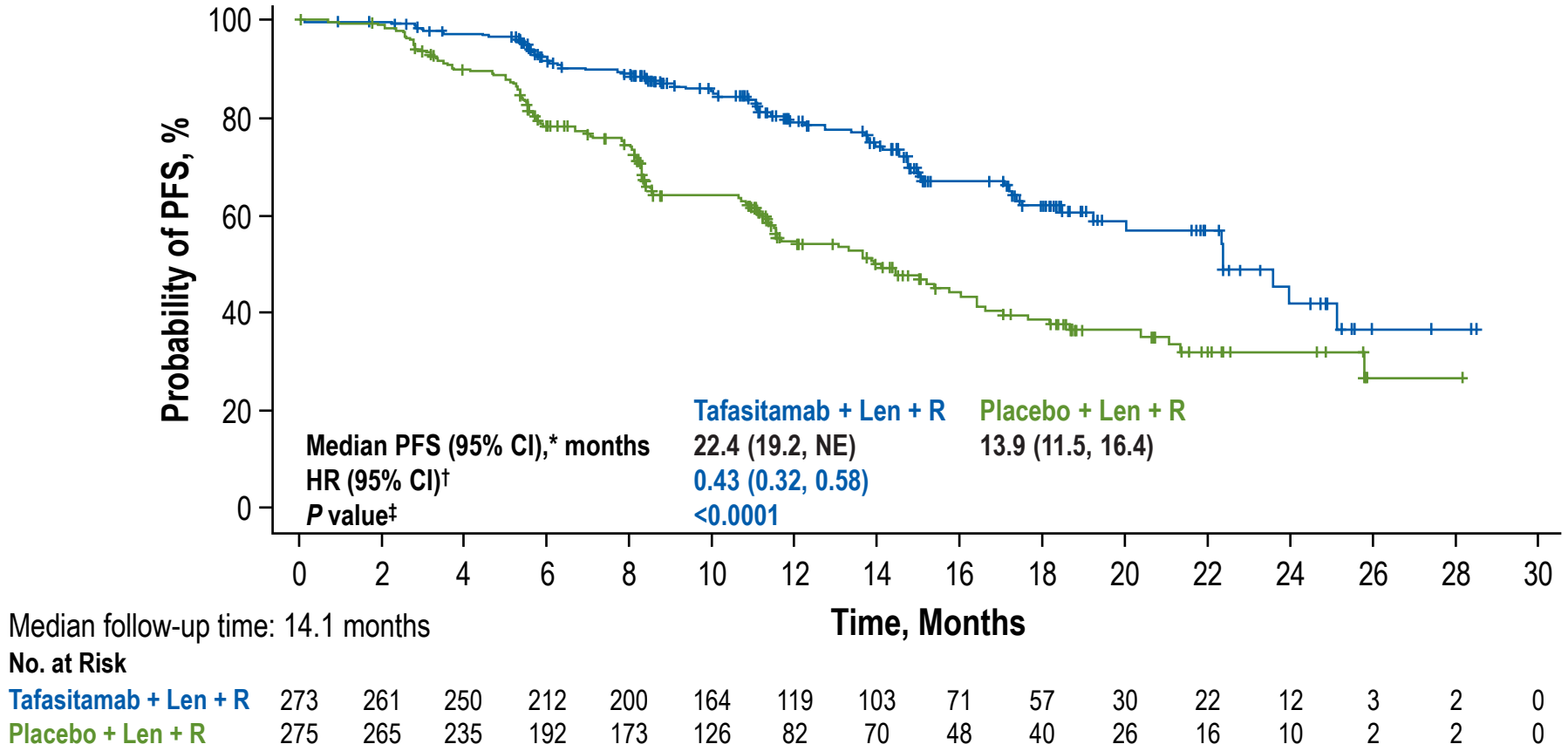
ITT population. ECOG PS= Eastern Cooperative Oncology Group performance status; FL= follicular lymphoma; FLIPI= Follicular Lymphoma International Prognostic Index; GELF= Groupe d'Etude des Lymphomes Folliculaires; ITT= intent-to-treat; Len= lenalidomide; R= rituximab

Treatment History

Variable	Tafasitamab + Len + R (n=273)	Placebo + Len + R (n=275)	Total (N=548)
Median number of prior lines of therapy (range)	1.0 (1, 7)	1.0 (1, 10)	1.0 (1, 10)
Number of prior lines of therapy, n (%)			
1	147 (53.8)	153 (55.6)	300 (54.7)
2	66 (24.2)	71 (25.8)	137 (25.0)
3	39 (14.3)	30 (10.9)	69 (12.6)
≥4	21 (7.7)	21 (7.6)	42 (7.7)
Time since last anti-lymphoma therapy, n (%)			
≤2 years	147 (53.8)	157 (57.1)	304 (55.5)
>2 years	126 (46.2)	118 (42.9)	244 (44.5)
POD24, n (%)	85 (31.1)	88 (32.0)	173 (31.6)
Relapsed/refractory status to last therapy, n (%)			
Relapsed	148 (54.2)	164 (59.6)	312 (56.9)
Refractory	112 (41.0)	97 (35.2)	209 (38.1)
Undetermined	13 (4.8)	14 (5.1)	27 (4.9)
Refractory to prior anti-CD20 therapy, n (%)	118 (43.2)	115 (41.8)	233 (42.5)

ITT population. ITT= intent-to-treat; Len= lenalidomide; POD24= disease progression within 24 months of initial diagnosis; R= rituximab

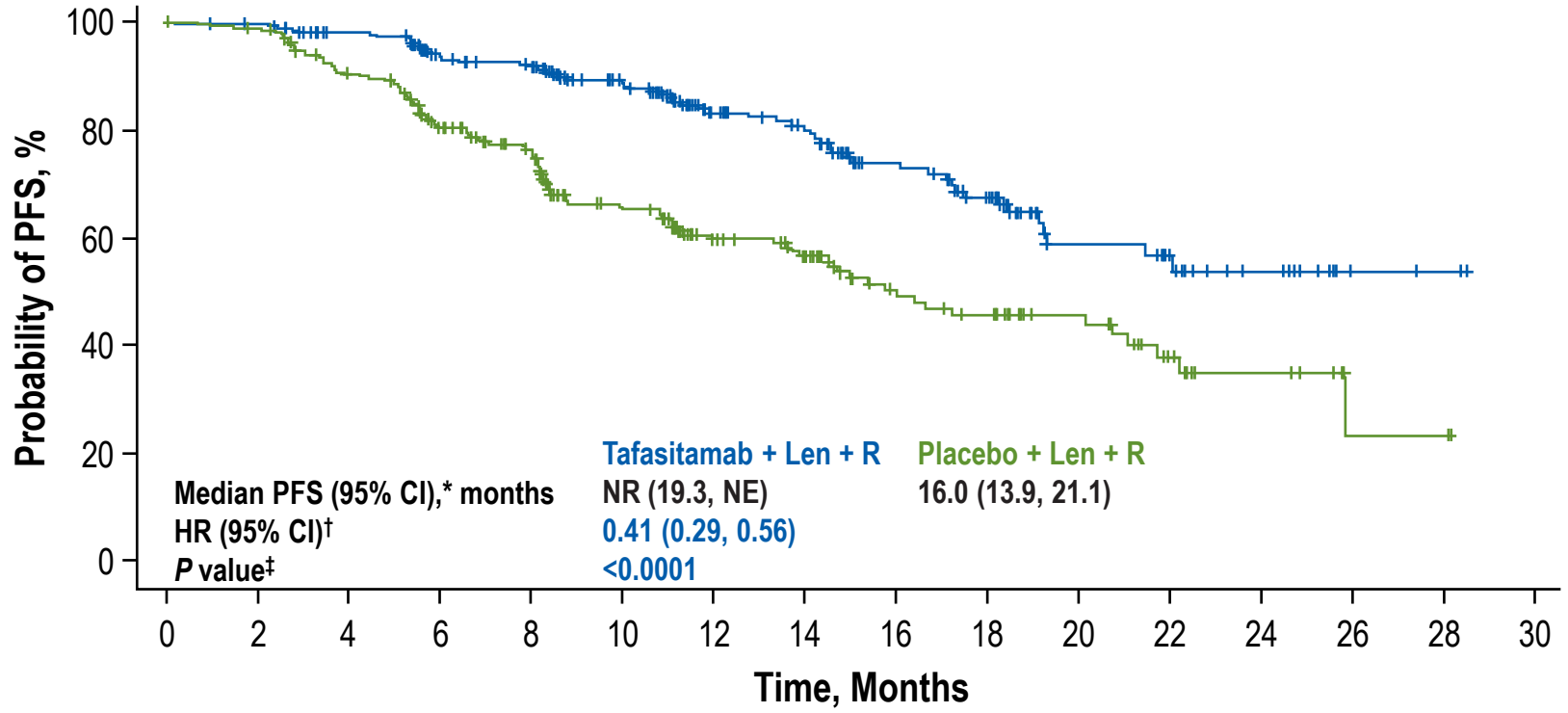
Primary Endpoint: PFS by Investigator Assessment



Significant improvement in PFS was observed with tafasitamab

ITT population. *Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. ‡Stratified log-rank test with a 2-sided significance level of 5%. CI= confidence interval; HR= hazard ratio; ITT= intent-to-treat; Len= lenalidomide; NE= not evaluable; PFS= progression-free survival; R= rituximab.

PFS by Independent Review Committee

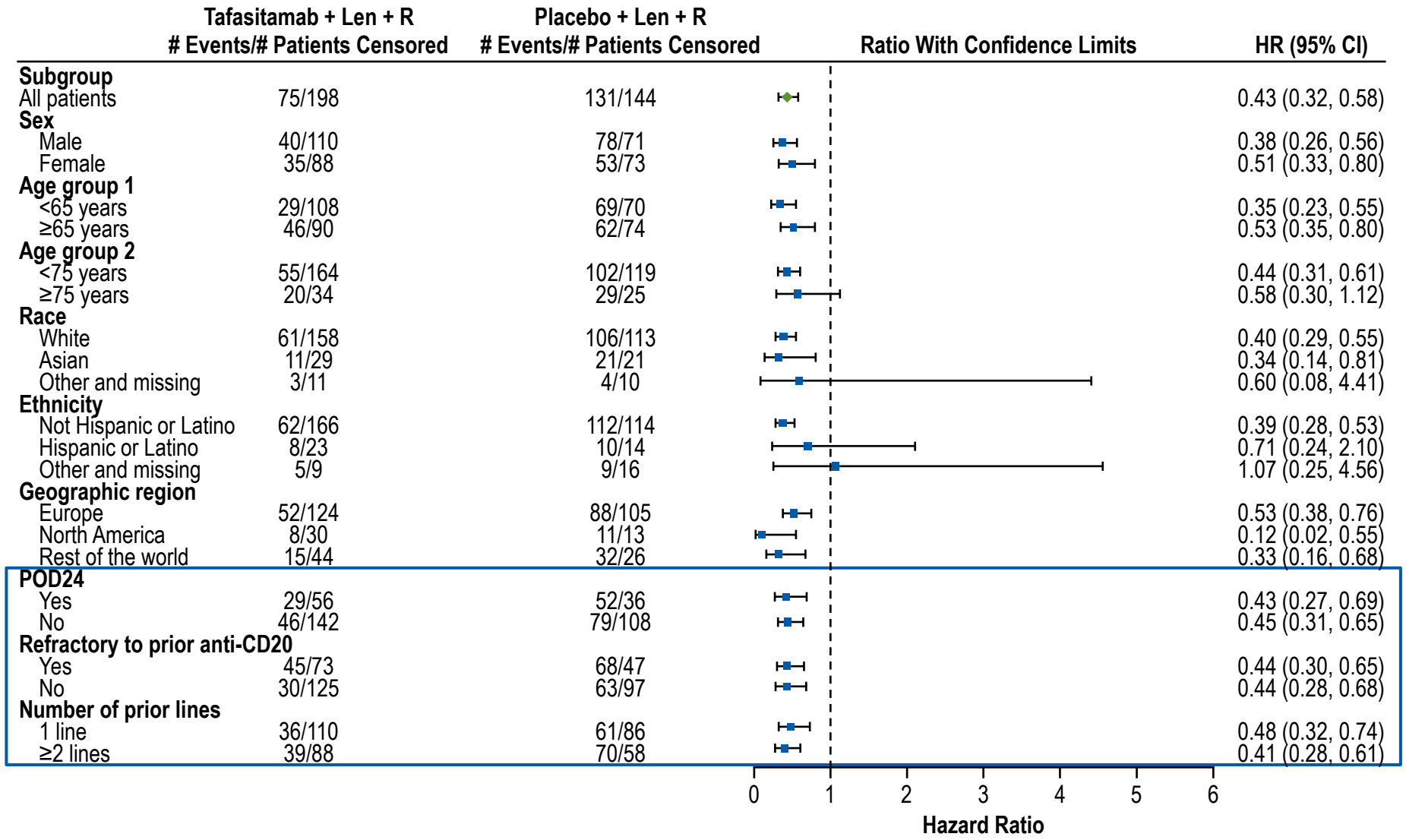


No. at Risk																
Tafasitamab + Len + R	273	260	246	210	200	162	113	98	72	58	28	20	12	3	2	0
Placebo + Len + R	275	260	230	193	170	120	79	67	44	38	26	15	8	2	2	0

Significant PFS benefit was confirmed by independent review committee

ITT population. *Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. ‡Nominal *P* value; stratified log-rank test with a 2-sided significance level of 5%.
CI= confidence interval; HR= hazard ratio; ITT= intent-to-treat; Len= lenalidomide; NE= not evaluable; NR= not reached; PFS= progression-free survival; R= rituximab

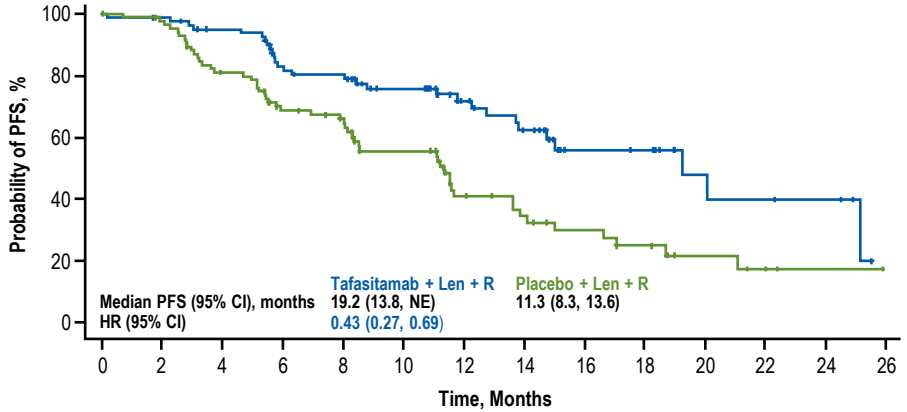
Prespecified Subgroup Analysis of PFS



ITT population. Analysis by investigator assessment. CI= confidence interval; HR= hazard ratio; ITT= intent-to-treat; Len= lenalidomide; PFS= progression-free survival; POD24= progression of disease within 24 months; R= rituximab

PFS by POD24 Status and Refractoriness to Anti-CD20

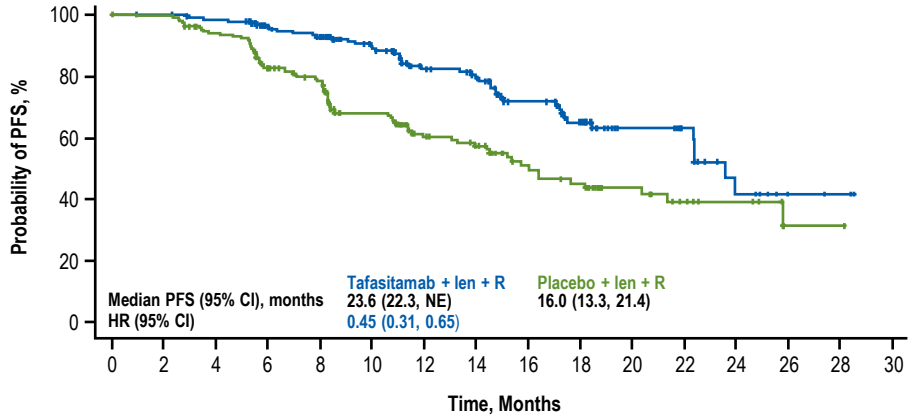
POD24: Yes



No. at Risk

Tafasitamab + Len + R	85	81	75	60	57	46	32	25	13	12	6	5	4	0
Placebo + Len + R	88	83	67	52	46	35	21	16	12	9	5	2	1	0

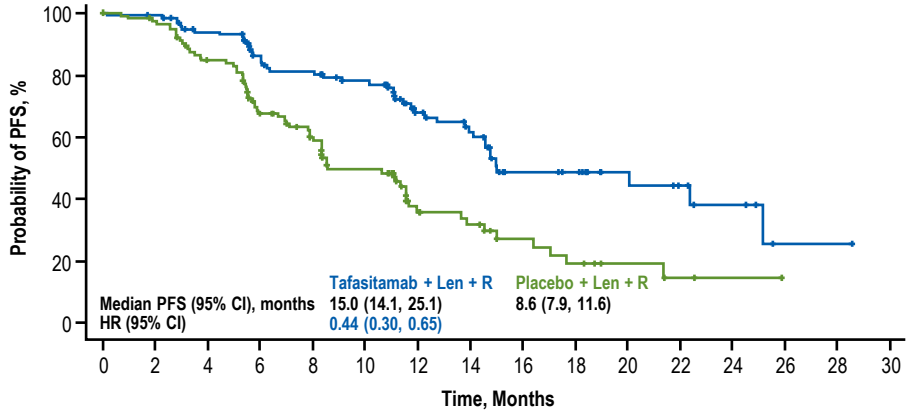
POD24: No



No. at Risk

Tafasitamab + Len + R	188	180	175	152	143	118	87	78	58	45	24	17	8	3	2	0
Placebo + Len + R	187	182	168	140	127	91	61	54	36	31	21	14	9	2	2	0

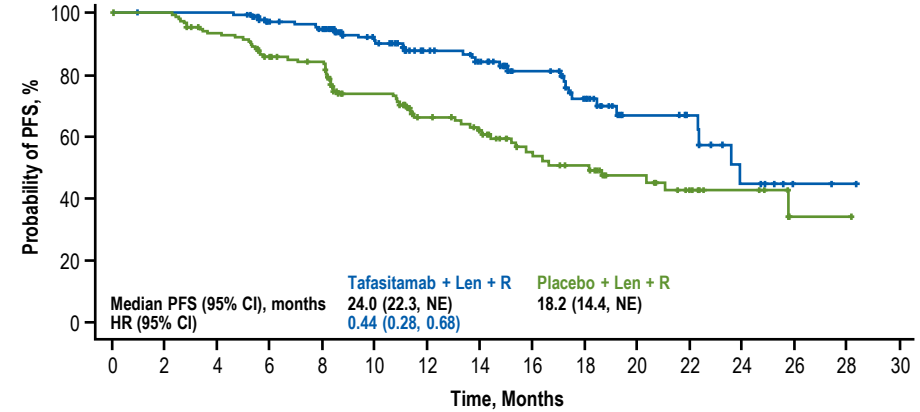
Anti-CD20 Refractory: Yes



No. at Risk

Tafasitamab + Len + R	118	113	102	86	80	71	46	38	21	19	11	8	5	1	1	0
Placebo + Len + R	115	108	91	66	54	41	20	16	10	7	4	2	1	0	0	0

Anti-CD20 Refractory: No



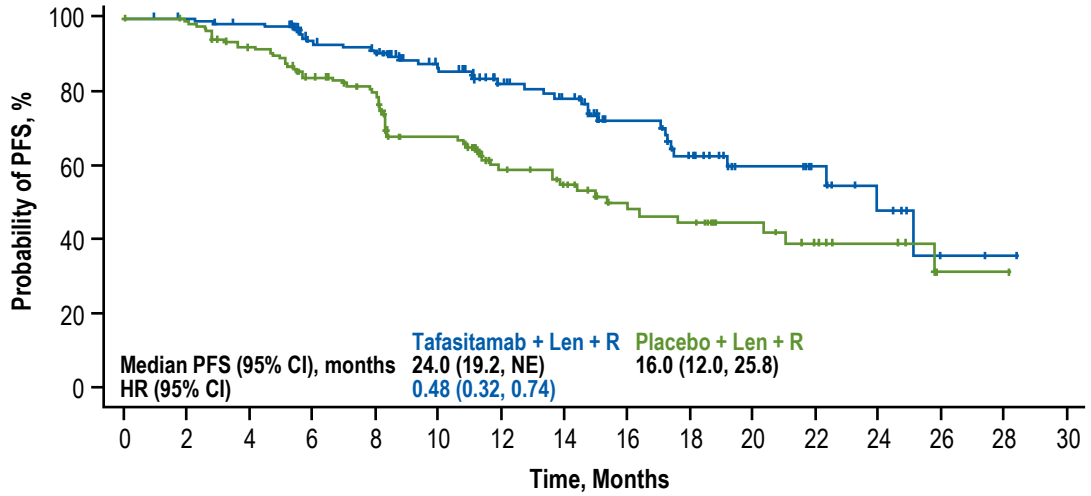
No. at Risk

Tafasitamab + Len + R	155	148	148	126	120	93	73	65	50	38	19	14	7	2	1	0
Placebo + Len + R	160	157	144	126	119	85	62	54	38	33	22	14	9	2	2	0

ITT population. Subgroup analyses are based on stratification factor. Analysis by investigator assessment. CI= confidence interval; HR= hazard ratio; ITT= intent-to-treat; Len= lenalidomide; NE= not evaluable; PFS= progression-free survival; POD24= progression of disease within 24 months of initial diagnosis; R= rituximab

PFS by Line of Therapy

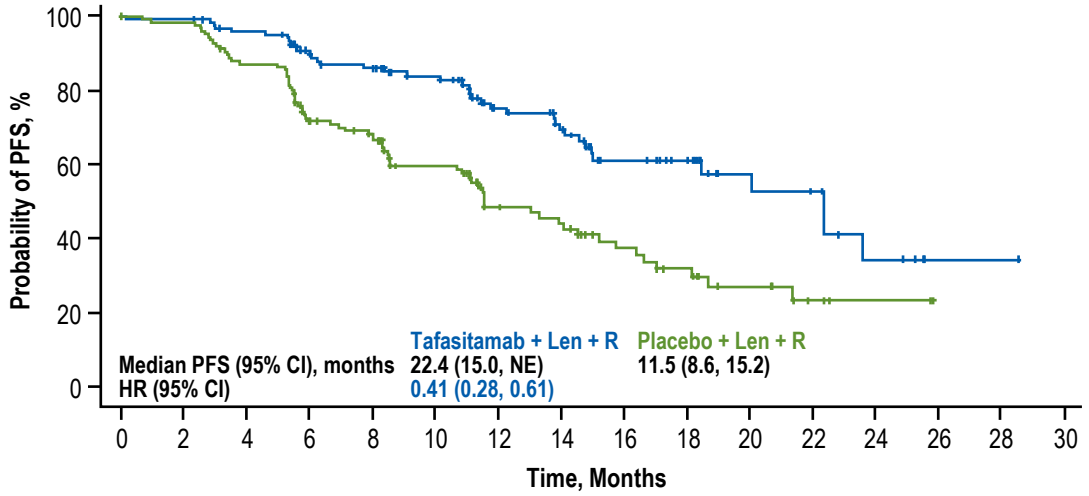
1 Prior Line (2L Treatment)



No. at Risk

Tafasitamab + Len + R	146	140	136	115	110	88	65	57	40	31	18	12	7	2	1	0
Placebo + Len + R	147	142	127	108	97	70	47	40	28	25	17	12	8	2	2	0

≥2 Prior Lines (3L+ Treatment)



No. at Risk

Tafasitamab + Len + R	127	121	114	97	90	76	54	46	31	26	12	10	5	1	1	0
Placebo + Len + R	128	123	108	84	76	56	35	30	20	15	9	4	2	0	0	0

ITT population. Subgroup analyses are based on stratification factor. Analysis by investigator assessment. 2L, second-line; 3L, third-line; CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; Len, lenalidomide; NE, not evaluable; PFS, progression-free survival; R, rituximab.

PET-CR and ORR

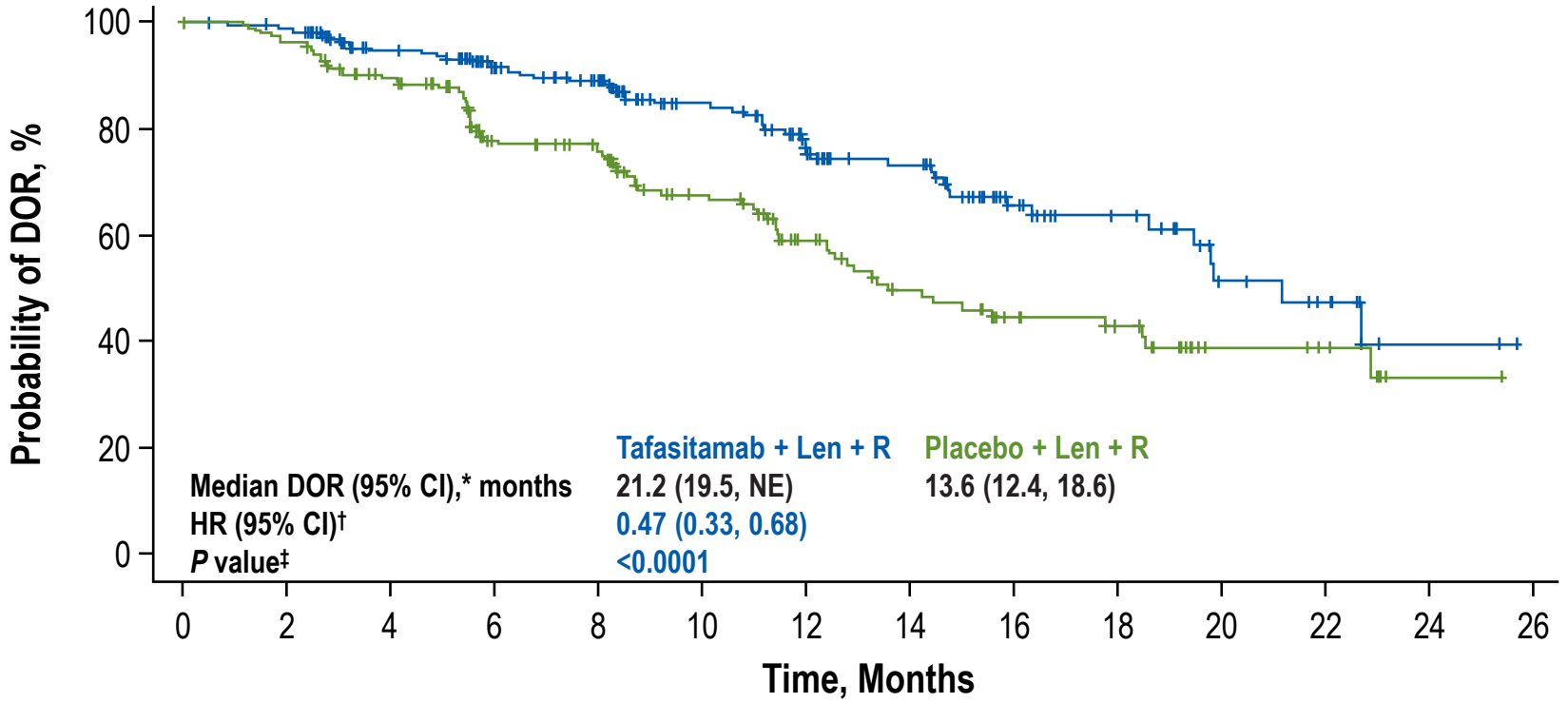
PET-CR (FDG-Avid Population)	Tafasitamab + Len + R	Placebo + Len + R
Patients with FDG-avid disease at baseline	251	254
Patients with postbaseline PET assessments, n (%)*	201/251 (80.1)	205/254 (80.7)
Best metabolic response based on PET, n (%)†		
CMR	124 (49.4)	101 (39.8)
PMR	37 (14.7)	39 (15.4)
NMR/SD	19 (7.6)	12 (4.7)
PMD	19 (7.6)	51 (20.1)
Not done	50 (19.9)	46 (19.3)
PET-CR rate, % (95% CI)	**49.4** (43.1, 55.8)	**39.8** (33.7, 46.1)
Odds ratio (95% CI)	**1.5 (1.04, 2.13)**	
Nominal *P* value	**0.0286**	

ORR (ITT Population)	Tafasitamab + Len + R	Placebo + Len + R
Patients, n	273	275
Best overall response, n (%)‡		
CR	142 (52.0)	112 (40.7)
PR	86 (31.5)	87 (31.6)
SD	28 (10.3)	46 (16.7)
PD	7 (2.6)	20 (7.3)
NE	2 (0.7)	0
Not done	8 (2.9)	10 (3.6)
ORR, % (95% CI)	**83.5** (78.6, 87.7)	**72.4** (66.7, 77.6)
Odds ratio (95% CI)	**2.0 (1.30, 3.02)**	
Nominal *P* value	**0.0014**	

Significant improvement in PET-CR rate and ORR was observed with tafasitamab

Analysis by investigator assessment. *Calculated based on patients with a positive PET scan at baseline, defined as having a Deauville score of 4 or 5 at baseline. †Two patients (0.8%) in both arms had PET after confirmed PD or new antilymphoma treatment initiation. ‡Per Lugano 2014 classification. CI= confidence interval; CMR= complete metabolic response; CR= complete response; FDG= fluorodeoxyglucose; ITT= intent-to-treat; Len= lenalidomide; NE= not evaluable; NMR= nonmetabolic response; ORR= overall response rate; PD= progressive disease; PET= positron emission tomography; PET-CR= positron emission tomography-complete response; PMD= progressive metabolic disease; PMR= partial metabolic response; PR= partial response; R= rituximab; SD= stable disease

Duration of Response

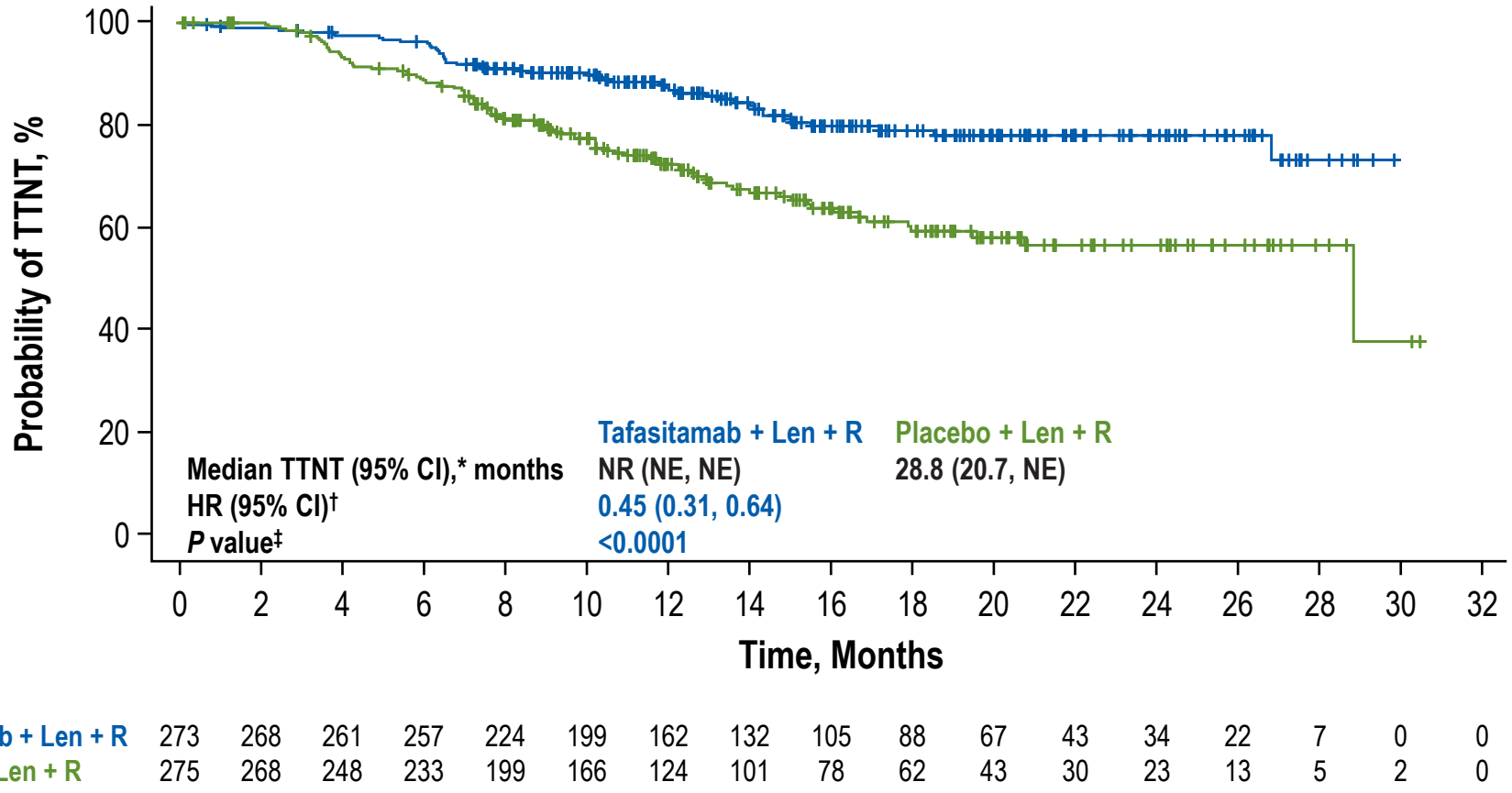


No. at Risk														
Tafasitamab + Len + R	228	219	185	155	140	105	81	66	37	27	14	10	3	0
Placebo + Len + R	199	188	163	115	106	75	54	40	29	22	10	8	2	0

Significant improvement in DOR was observed with tafasitamab

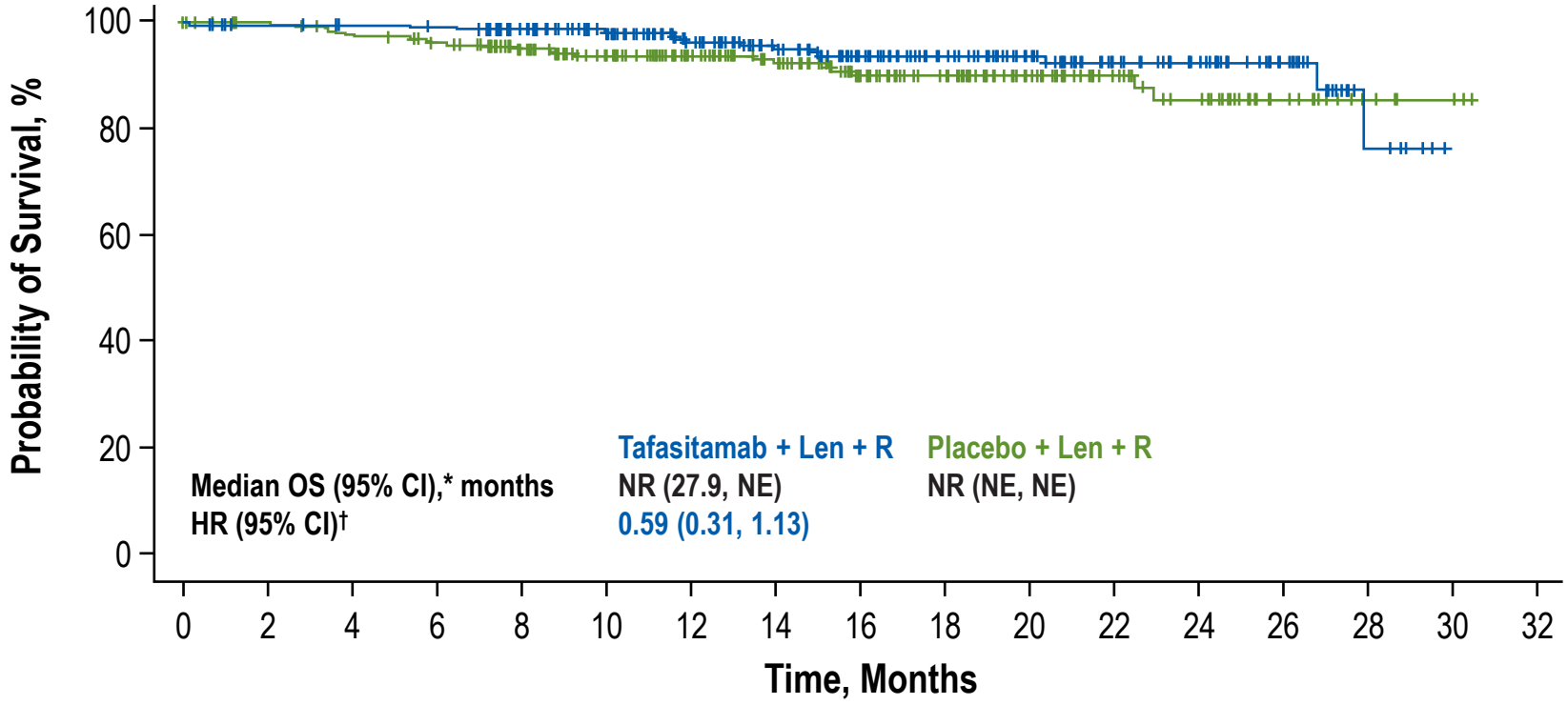
ITT population. Analysis by investigator assessment. *Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. ‡Nominal *P* value; stratified log-rank test with a 2-sided significance level of 5%. CI= confidence interval; DOR= duration of response; HR= hazard ratio; ITT= intent-to-treat; Len= lenalidomide; NE= not evaluable; R= rituximab

Time to Next Treatment



ITT population. Analysis by investigator assessment. *Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. ‡Nominal *P* value; stratified log-rank test with a 2-sided significance level of 5%. CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; len, Lenalidomide; NE, not evaluable; NR, not reached; R, rituximab; TTNT, time to next treatment.

Overall Survival



- OS was tested only for futility at the time of the primary analysis
- After a median follow-up of 15.3 months, the futility threshold was not crossed and a positive trend was observed

ITT population. Analysis by investigator assessment. *Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. CI= confidence interval; HR= hazard ratio; ITT= intent-to-treat; Len= lenalidomide; NE= not evaluable; NR= not reached; OS= overall survival; R= rituximab

Most Frequent Any-Grade TEAEs (≥15% in Any Group)

Preferred Term, n (%)	Tafasitamab + Len + R (n=274)*	Placebo + Len + R (n=272)†	Total (n=546)
Any adverse event	272 (99.3)	270 (99.3)	542 (99.3)
Neutropenia	133 (48.5)	123 (45.2)	256 (46.9)
Diarrhea	103 (37.6)	77 (28.3)	180 (33.0)
COVID-19	86 (31.4)	64 (23.5)	150 (27.5)
Constipation	80 (29.2)	67 (24.6)	147 (26.9)
Rash	60 (21.9)	58 (21.3)	118 (21.6)
Fatigue	58 (21.2)	43 (15.8)	101 (18.5)
Cough	52 (19.0)	47 (17.3)	99 (18.1)
Pyrexia	52 (19.0)	44 (16.2)	96 (17.6)
Muscle spasms	49 (17.9)	49 (18.0)	98 (17.9)
Nausea	49 (17.9)	38 (14.0)	87 (15.9)
Infusion-related reaction	43 (15.7)	41 (15.1)	84 (15.4)
Thrombocytopenia	37 (13.5)	42 (15.4)	79 (14.5)
Pruritus	44 (16.1)	28 (10.3)	72 (13.2)

Safety population. *One patient randomized to the placebo + len + R group is included in the tafasitamab + len + R safety population because the patient erroneously received tafasitamab. †Three patients randomized to the placebo + len + R group are not included in the safety population because they erroneously received tafasitamab (n=1), or did not receive any study treatment due to confirmation of R hypersensitivity (n=1), or the patient withdrew from the study (n=1). COVID-19= coronavirus disease 2019; Len= lenalidomide; R= rituximab; TEAE= treatment-emergent adverse event

Grade 3 or 4 TEAEs and Dose Modifications

Preferred Term, n (%)	Tafasitamab + Len + R (n=274)*	Placebo + Len + R (n=272)†	Total (n=546)
Neutropenia	109 (39.8)	102 (37.5)	211 (38.6)
Pneumonia	23 (8.4)	14 (5.1)	37 (6.8)
Thrombocytopenia	17 (6.2)	20 (7.4)	37 (6.8)
Neutrophil count decreased	16 (5.8)	18 (6.6)	34 (6.2)
Anemia	12 (4.4)	16 (5.9)	28 (5.1)
COVID-19	16 (5.8)	6 (2.2)	22 (4.0)
COVID-19 pneumonia	13 (4.7)	3 (1.1)	16 (2.9)

- Tafasitamab and placebo dose interruptions or discontinuations due to TEAEs were similar between treatment arms, n (%):
  - Dose delay or interruption due to TEAEs: 203 (74%) vs 190 (70%)
  - Discontinued study treatment due to TEAEs: 30 (11%) vs 18 (7%)
- Len discontinuations due to TEAEs were similar between tafasitamab and placebo arms, n (%):
  - 39 (14%) vs 31 (11%)
- Len dose reductions were similar between tafasitamab and placebo arms
  - Median relative dose intensity: 86% vs 87%

Safety population. *One patient randomized to the placebo + len + R group is included in the tafasitamab + len + R safety population because the patient erroneously received tafasitamab. †Three patients randomized to the placebo + len + R group are not included in the safety population because they erroneously received tafasitamab (n=1), or did not receive any study treatment due to confirmation of R hypersensitivity (n=1), or the patient withdrew from the study (n=1). COVID-19= coronavirus disease 2019; Len= lenalidomide; R= rituximab; TEAE= treatment-emergent adverse event

Summary of Deaths and Fatal TEAEs

Variable, n (%)	Tafasitamab + Len + R (n=274)*	Placebo + Len + R (n=272)†	Total (n=546)
All deaths	**15 (5.5)**	**23 (8.5)**	38 (7.0)
Disease progression	**5 (1.8)**	**17 (6.3)**	22 (4.0)
Adverse event with fatal outcome	**6 (2.2)**	**6 (2.2)**	12 (2.2)
COVID-19	2 (0.7)	0	2 (0.4)
COVID-19 pneumonia	0	2 (0.7)	2 (0.4)
Sepsis	1 (0.4)	1 (0.4)	2 (0.4)
Adenocarcinoma gastric	1 (0.4)	0	1 (0.2)
Carcinoid tumor (large intestine)	1 (0.4)	0	1 (0.2)
Death‡	1 (0.4)	0	1 (0.2)
Bronchopulmonary aspergillosis	0	1 (0.4)	1 (0.2)
Cardiac failure	0	1 (0.4)	1 (0.2)
Pneumonia	0	1 (0.4)	1 (0.2)
Deaths reported after 90-day follow-up interval	4 (1.5)	0	4 (0.7)
Heart failure	1 (0.4)	0	1 (0.2)
Lung infection	1 (0.4)	0	1 (0.2)
Pneumonia	1 (0.4)	0	1 (0.2)
Respiratory failure	1 (0.4)	0	1 (0.2)

Safety population. *One patient randomized to the placebo + len + R group is included in the tafasitamab + len + R safety population because the patient erroneously received tafasitamab. †Three patients randomized to the placebo + len + R group are not included in the safety population because they erroneously received tafasitamab (n=1), or did not receive any study treatment due to confirmation of R hypersensitivity (n=1), or the patient withdrew from the study (n=1). ‡This is an unexplained death case, not related to any TEAE or other event. COVID-19= coronavirus disease 2019; Len= lenalidomide; R= rituximab; TEAE= treatment-emergent adverse event

FL Patient Population Comparison

Variable	inMIND Tafasitamab + Len + R (n=273)	inMIND Placebo + Len + R (n=275)	AUGMENT[1] R + Len (n=147)
Median age, years	64	64	62
Male, %	55	54	42
Ann Arbor stage IV at enrollment, %	55	59	30
FL grade 3A, %	25	26	12
FLIPI high risk (score 3-5) , %	50	55	37
ECOG PS 0, %	66	70	67
ECOG PS 1-2, %	34	30	33
B symptoms present, %	23	24	8
High tumor burden per GELF (yes), %	81	84	52
Refractory to last prior regimen, %	41	35	18
Refractory to anti-CD20, %	43	42	–

1, Leonard JP, et al. *J Clin Oncol.* 2019;37:1188-1899.
ECOG PS= Eastern Cooperative Oncology Group performance status; FL= follicular lymphoma; FLIPI= Follicular Lymphoma International Prognostic Index; GELF= Groupe d'Etude des Lymphomes Folliculaires; len= lenalidomide; R= rituximab

Conclusions

- The inMIND phase 3 study met its primary endpoint of prolonging PFS in R/R FL
  - Addition of tafasitamab to lenalidomide and rituximab resulted in significant improvement in PFS, representing a 57% reduction in risk of progression, relapse, or death
  - Benefit was observed in all prespecified subgroups, including patients with POD24, refractory to prior anti-CD20 mAbs, and receiving multiple prior lines of therapy
- Although OS data are immature, a trend in favor of tafasitamab was observed
- The safety profile was manageable and consistent with expected toxicities with these agents
- This study is the first to validate the approach of combining 2 antibodies (anti-CD19 with anti-CD20) for treatment of FL
- Tafasitamab plus lenalidomide and rituximab can be administered in community as well as academic settings and represents a potential new standard of care for patients with R/R FL

FL= follicular lymphoma; mAb= monoclonal antibody; OS= overall survival; PFS= progression-free survival; POD24= disease progression within 24 months of initial diagnosis; R/R= relapsed or refractory

Additional Development Updates

Steven Stein
Chief Medical Officer

BETi Phase 3 Development Plan

- File an NDA and secure approval in patients with MF before 2029 (US)
- Pivotal program will initially evaluate BETi in:
  - A Phase 3 monotherapy study in post JAK population (relapsed/refractory/intolerant)
    - Future plans: Potentially evaluate BETi in a Phase 3 study in combination with RUX in 1L JAK-naïve population
- Phase 3 post JAK study concept submitted to the FDA in **4Q'24**

Next Steps

- Initiate a Phase 3 monotherapy study in post JAK population in **2025**
- Pending regulatory discussions and further data, disclose potential development path for the 1L JAK-naïve study

NDA= new drug application; MF= myelofibrosis

Potential Phase 3 Study Design: Post-JAK

A randomized, open-label study vs BAT

Primary Endpoint: SVR35 at week 24
Key Secondary: TSS50 at week 24

*Block randomization with stratification for the following:

- Anemia (Hgb ≥ 10 vs Hgb < 10)
- DIPSS category (Int-2 vs high)

SVR35= Spleen volume response defined as ≥35% reduction from baseline (MRI or CT) after 24 weeks; TSS50= total symptom score response defined as ≥50% total symptom score reduction from baseline after 24-weeks

Near-Term Opportunities for Tafasitamab

Practice changing potential in relapsed/refractory follicular lymphoma

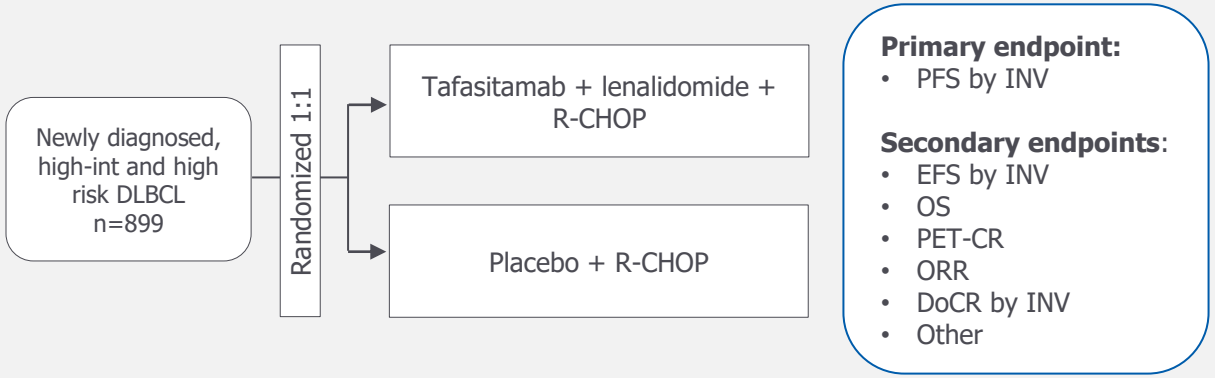
Follicular Lymphoma

- Phase 3 *inMIND* trial met its primary endpoint
  - Progression-free survival (PFS) in r/r FL
    - 57% reduction in risk of progression, relapse or death
  - Observed in all prespecified subgroups
- Favorable trend in overall survival – data still immature
- Manageable safety profile
- First study to validate the approach of combining anti-CD19 with anti-CD20 for the treatment of FL
- Potential to address approximately 23,000 pts with r/r FL in the U.S. and Europe

Next Steps

- sBLA filing in FL by year-end **2024**
- Potential **FDA Approval** anticipated in **2H'25**

Diffuse Large B-Cell Lymphoma



- Potential to address approximately 32,000 pts with 1L DLBCL (IPI 3-5) in the U.S. and Europe

Next Steps

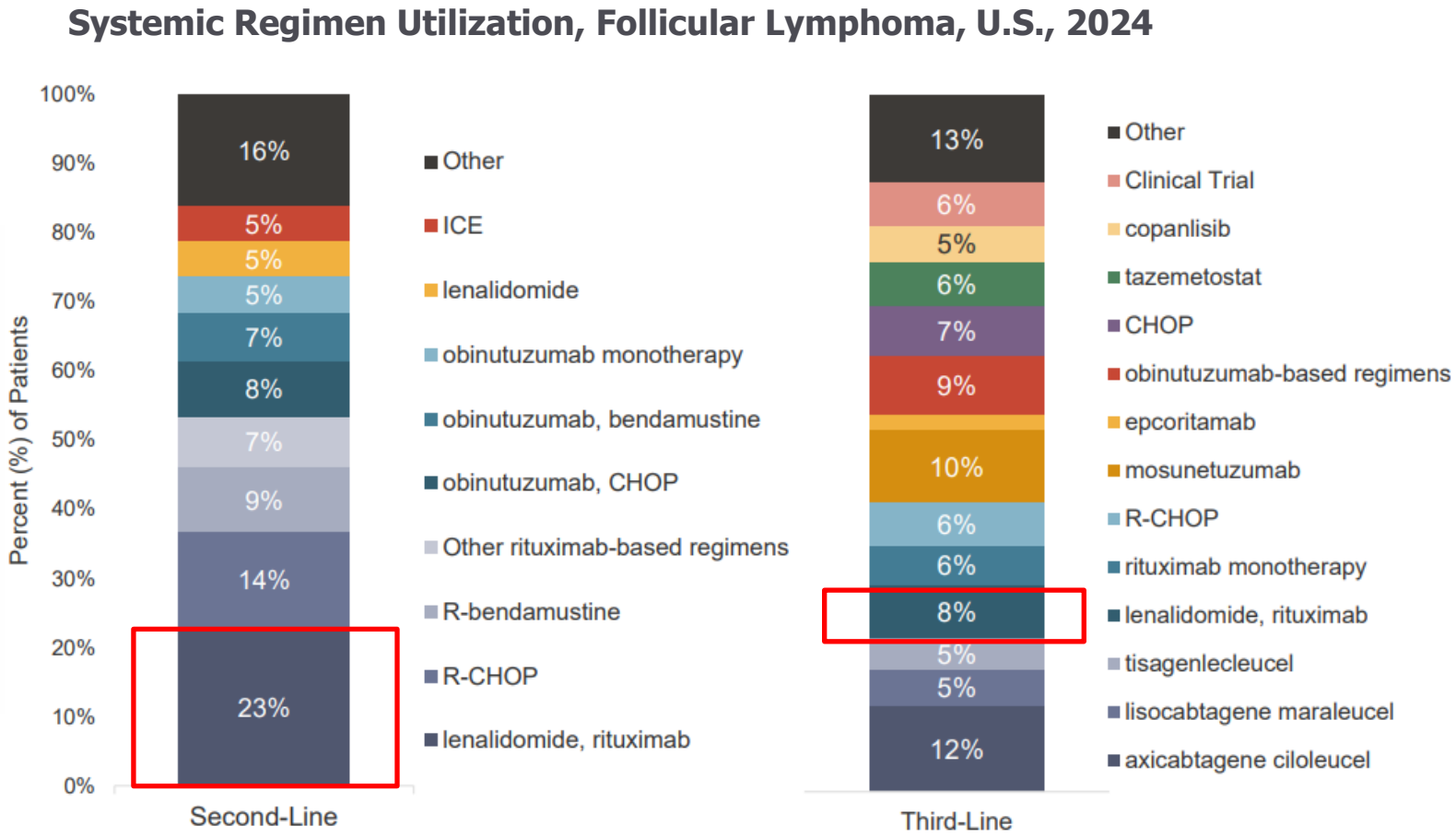
- Phase 3 data in 1L DLBCL anticipated in **1H'25**

R-CHOP= rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine sulfate and prednisone; CHOP= cyclophosphamide, doxorubicin hydrochloride, vincristine sulfate and prednisone; PFS= progression-free survival; INV= investigator; EFS= event-free survival; OS= overall survival; ORR= overall response rate; DoCR= duration of complete response; IPI= International Prognostic Index

Opportunity for Significant Market Penetration

For tafasitamab in relapsed/refractory follicular lymphoma

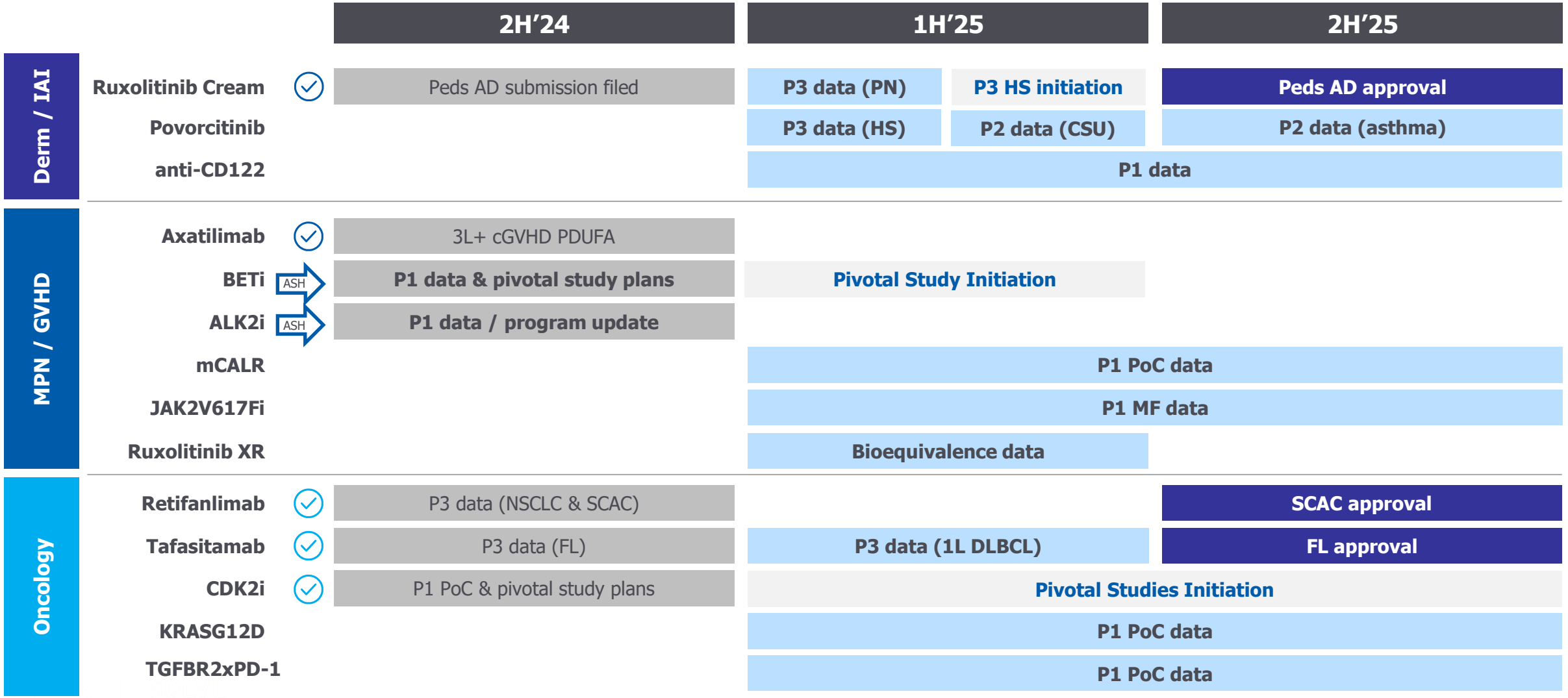
- Fragmented treatment landscape
- R^2 remains the most prescribed regimen in 2L r/r follicular lymphoma
- Potential for tafasitamab to achieve significant market penetration



CancerMPact. April 2024. Incyte data on file.

R^2 = lenalidomide + rituximab; R-CHOP= rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine sulfate and prednisone; CHOP= cyclophosphamide, doxorubicin hydrochloride, vincristine sulfate and prednisone; ICE= ifosfamide, carboplatin and etoposide phosphate

2025 Major Data Milestones



MPN= myeloproliferative neoplasms; GVHD= graft-versus-host disease; IAI= inflammation and autoimmunity; NSCLC= non-small cell lung cancer; SCAC= squamous cell anal carcinoma; FL= follicular lymphoma; PoC= proof-of-concept; DLBCL= diffuse large B-cell lymphoma; AD= atopic dermatitis; PN= prurigo nodularis; HS= hidradenitis suppurativa; CSU= chronic spontaneous urticaria

Q&A

Incyte

Solve On.