Data Highlights from ASH 2020

MONDAY, DECEMBER 7, 2020
10.00-11.30AM EASTERN

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 without limitation statements regarding: our expectations regarding our multiple opportunities to drive growth and diversification; implications for cGVHD therapy from the REACH3 clinical trial and potential uses of ruxolitinib for the treatment of cGVHD; the potential for further growth for ruxolitinib and for ruxolitinib to treat previously unstudied populations; the potential, the size of the opportunity, and the expected timing of NDA submission, for parsaclisib for the treatment of r/r non-Hodgkin lymphoma; the potential for increased antitumor activity with tafasitamab and parsaclisib; the potential for combination opportunities for ruxolitinib; and the expected timing of results from, and start dates for clinical trials of, tafasitamab. These forward-looking statements are based on our current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; determinations made by the FDA; the acceptance of our products and the products of our collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in our reports filed with the U.S. Securities and Exchange Commission, including our quarterly report on Form 10-Q for the quarter ended September 30, 2020. We disclaim any intent or obligation to update these forward-looking statements.

AGENDA & WELCOME

STEVEN STEIN, MD

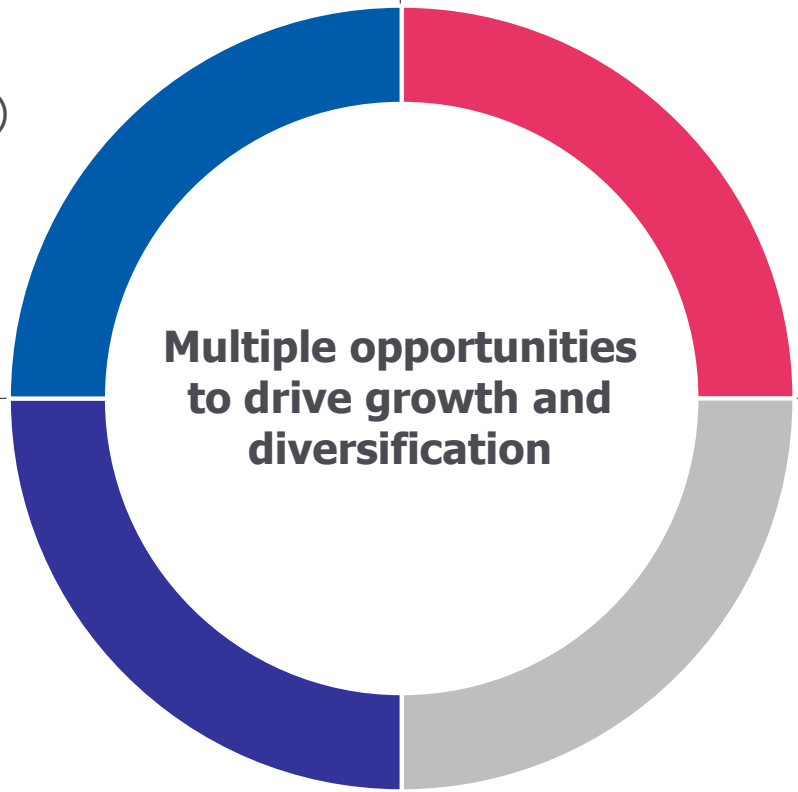
CHIEF MEDICAL OFFICER, INCYTE

MPNs and GVHD

- JAKAFI® (ruxolitinib)
- QD ruxolitinib
- Combinations (PI3Kδ, BET, ALK2)
- New targets

Dermatology

- ruxolitinib cream
- INCB54707 (JAK1)



Hematology/Oncology

- MONJUVI® (tafasitamab-cxix)
- PEMAZYRE® (pemigatinib)
- parsaclisib (PI3Kδ)
- retifanlimab (PD-1); INCB86550 (PD-L1)

Royalties

- JAKAVI® (ruxolitinib)
- TABRECTA™ (capmatinib)
- OLUMIANT® (baricitinib)

Incyte | SOLVE ON.

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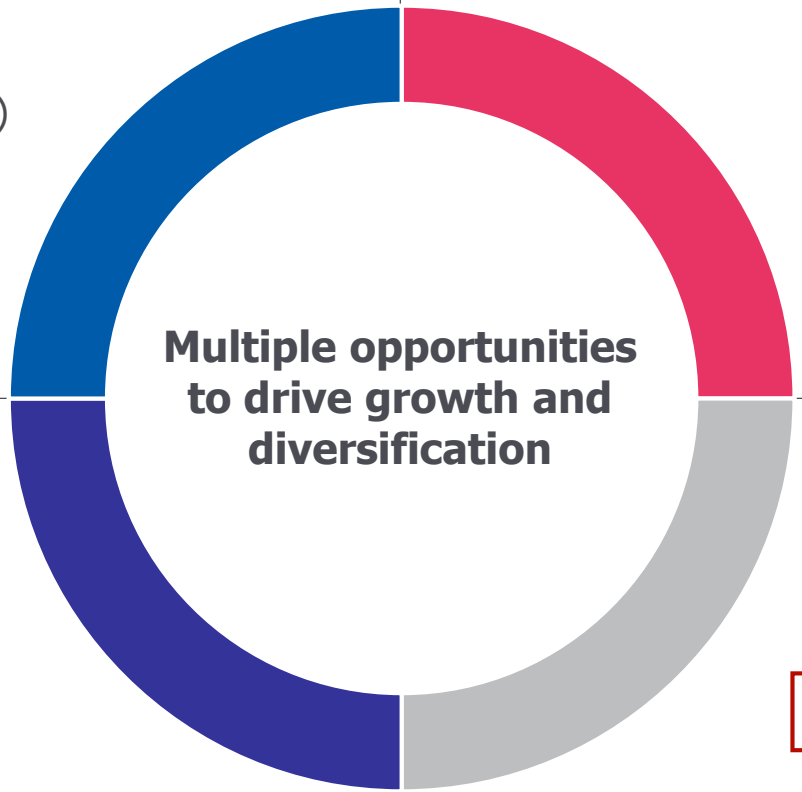

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AGENDA FOR TODAY'S WEBCAST

MULTIPLE LATE-STAGE OPPORTUNITIES IN HEMATOLOGY/ONCOLOGY

10.00-10.30	Prof. Dr. Robert Zeiser	**ruxolitinib** (JAK1/JAK2) Chronic GVHD, results from REACH3 and implications for therapy
	Q&A	
10.30-11.30	Steven Stein, MD	**ruxolitinib** (JAK1/JAK2) Long-term outcomes data in MF (EXPAND) and PV (RESPONSE-2)
	Peter Langmuir, MD	**parsaclisib** (PI3Kδ) CITADEL data, timelines and combination opportunities
		tafasitamab (CD19) L-MIND, firstMIND and development plans in DLBCL and beyond
	Q&A	

CHRONIC GVHD

PROF. DR. ROBERT ZEISER

HEAD OF THE SECTION OF TUMOR IMMUNOLOGY AND IMMUNE MODULATION
UNIVERSITY OF FREIBURG, GERMANY

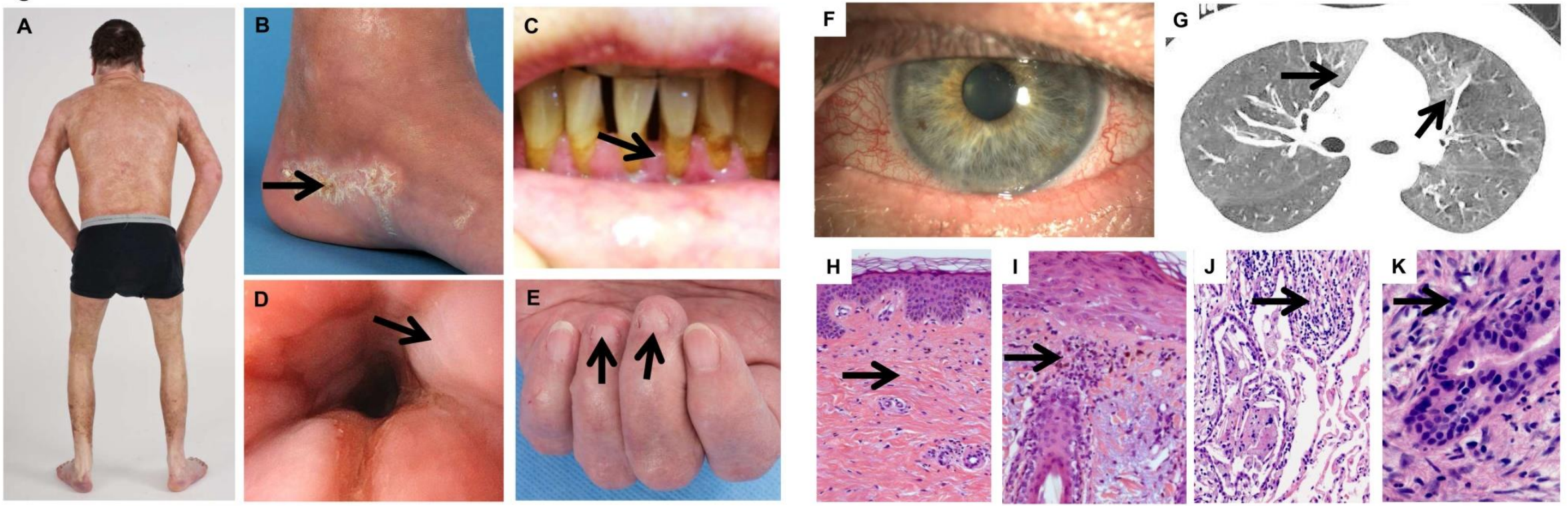
Ruxolitinib for chronic GVHD

Prof. Robert Zeiser

Universitätsklinikum Freiburg
Klinik für Hämatologie, Onkologie und Stammzelltransplantation

Clinical features of chronic GVHD

Figure 1



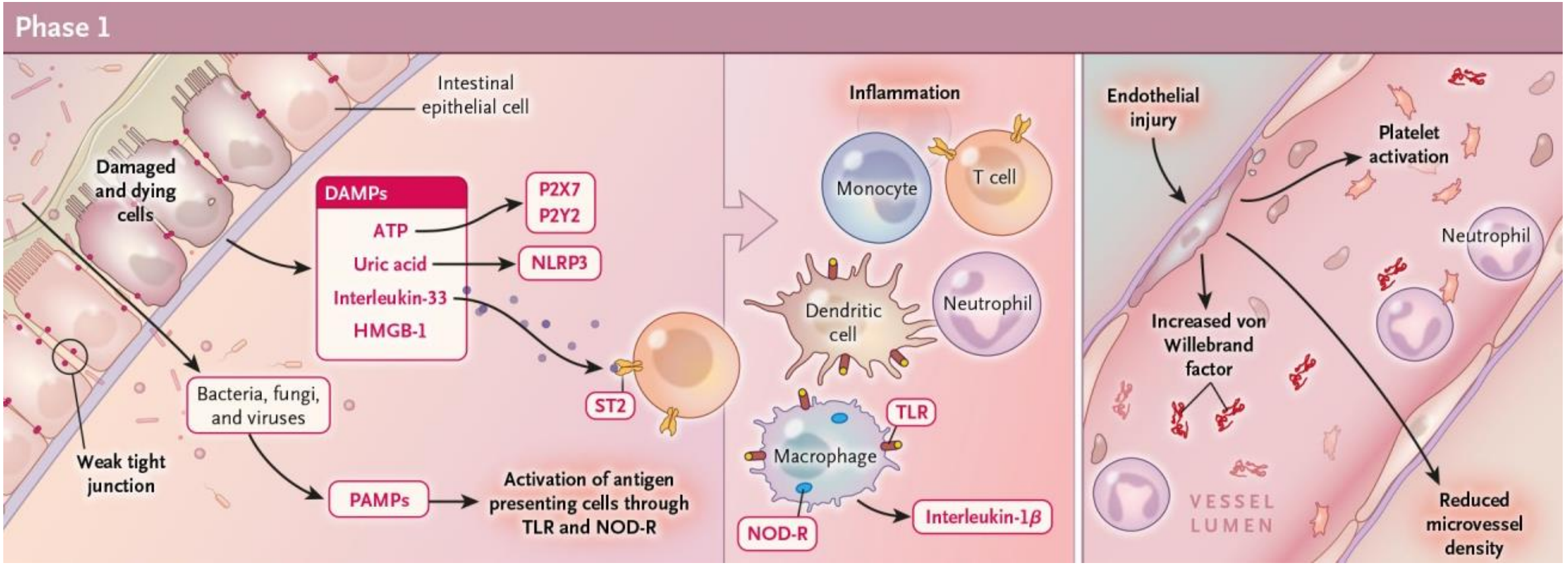
Zeiser R, Blazar B NEJM 2017

Background on cGVHD

- cGVHD occurs in approximately 30% to 70% of patients who undergo alloSCT[1] and is a leading cause of nonrelapse mortality and morbidity[2,3]
- Standard first-line therapy consists of systemic glucocorticoids; however, approximately 50% of patients become refractory or dependent[4]
- No standard second-line treatment has been defined and there have been no successful, large scale, randomized studies in this setting

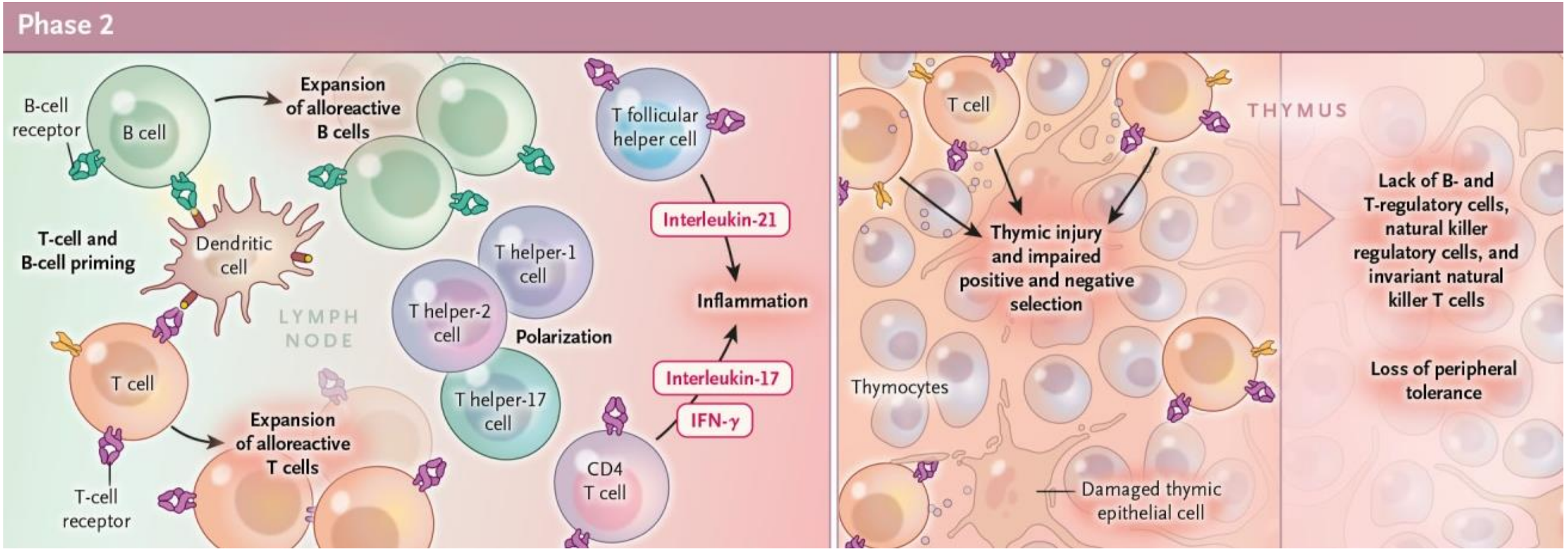
1. Arora M, et al. *Biol Blood Marrow Transplant*. 2016;22:449-55. 2. Lee SJ, et al. *Blood.* 2002;100:2697-702.
3. Zeiser R, Blazar BR. *N Engl J Med*. 2017;377:2565-79. 4. Axt L, et al. *Bone Marrow Transplant*. 2019;54:1805-14.

Pathomechanism of chronic GVHD: Phase 1



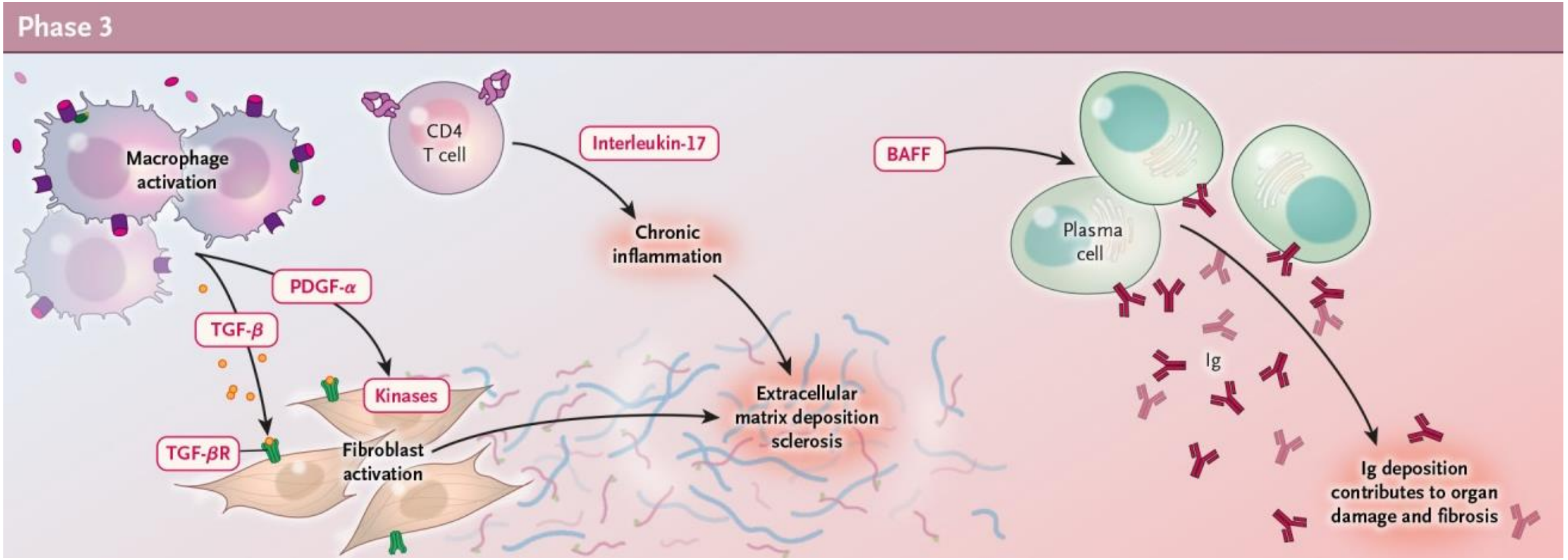
Zeiser R, Blazar B NEJM 2017

Pathomechanism of chronic GVHD: Phase 2



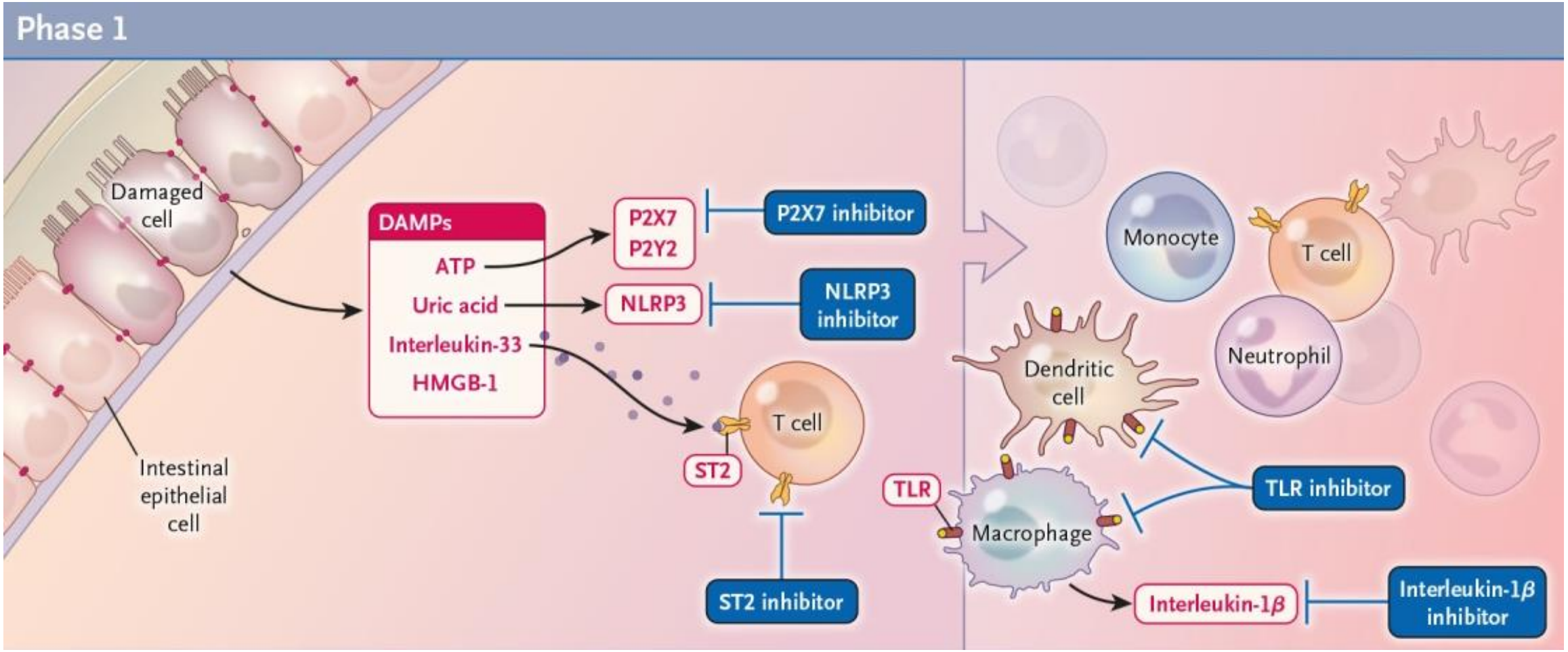
Zeiser R, Blazar B NEJM 2017

Pathomechanism of chronic GVHD: Phase 3



Zeiser R, Blazar B NEJM 2017

New Targets in chronic GVHD



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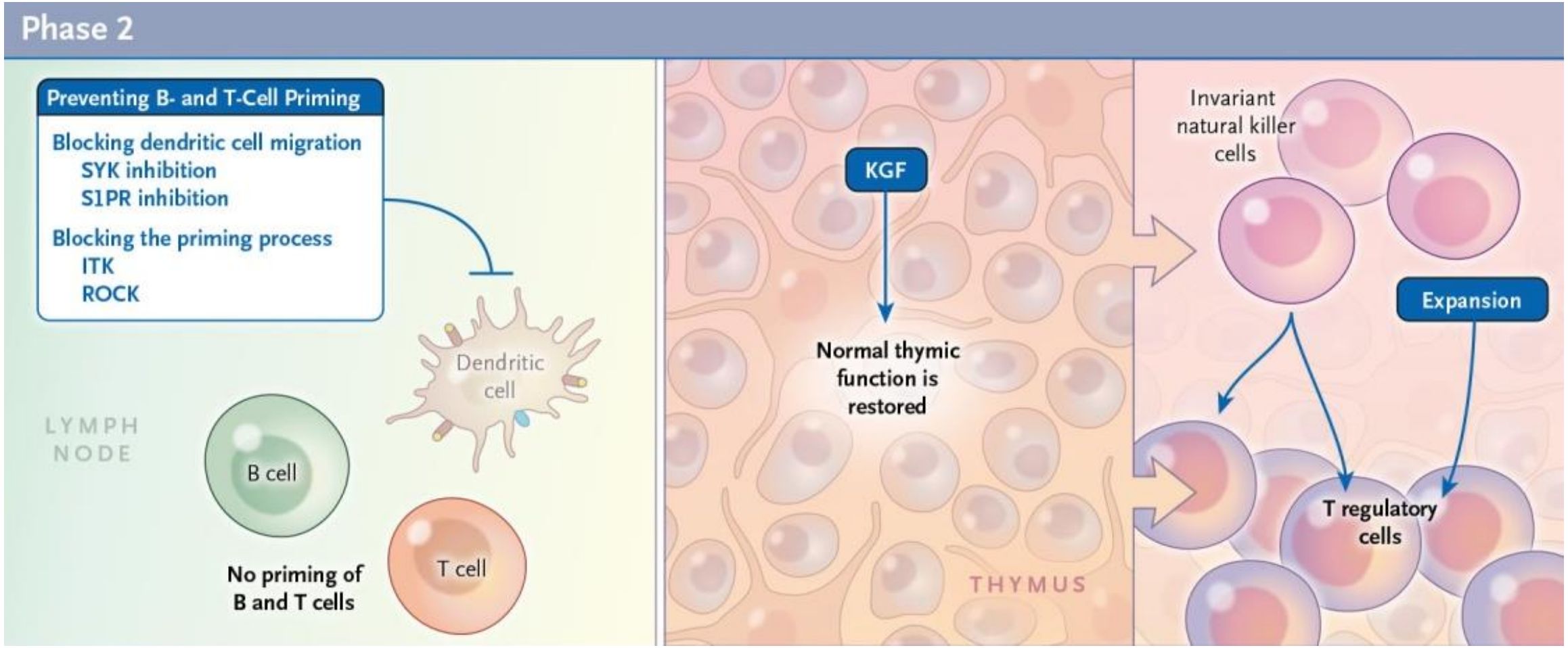

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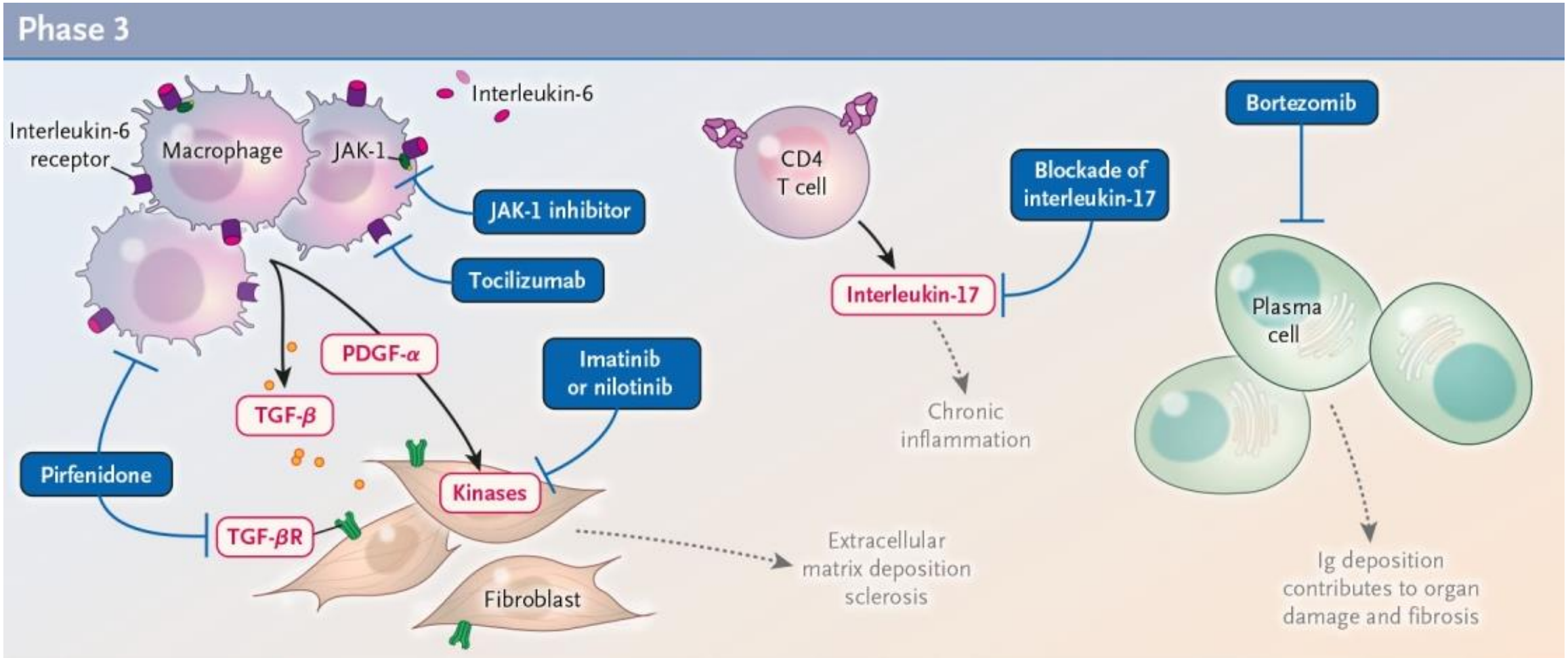
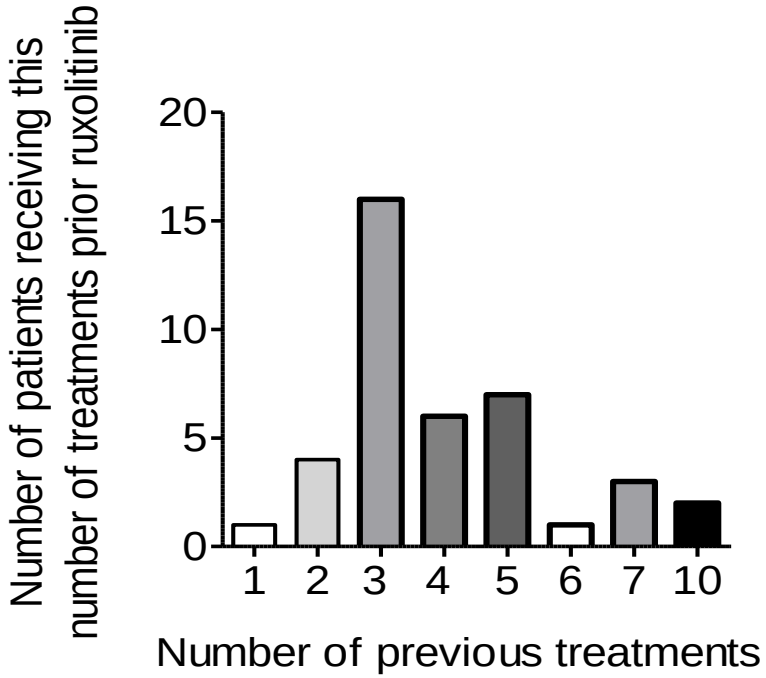
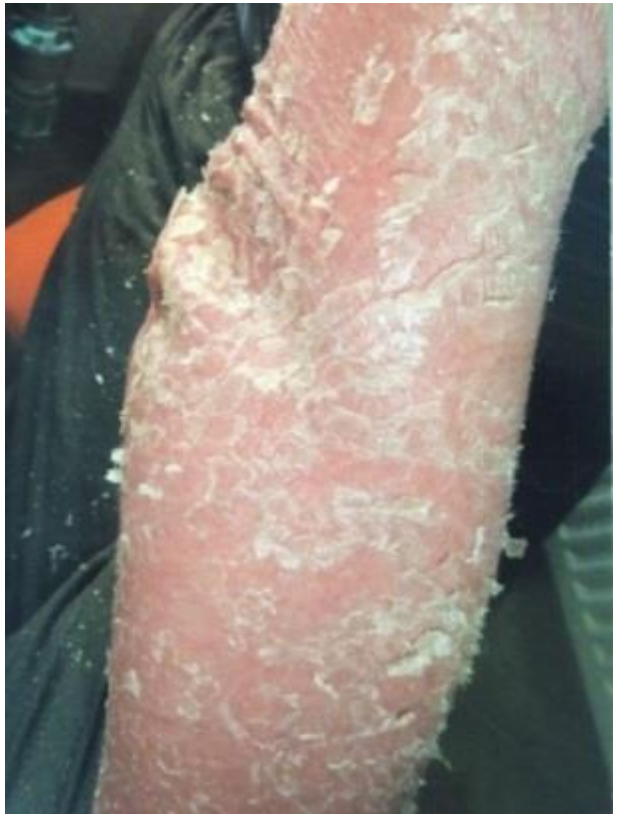
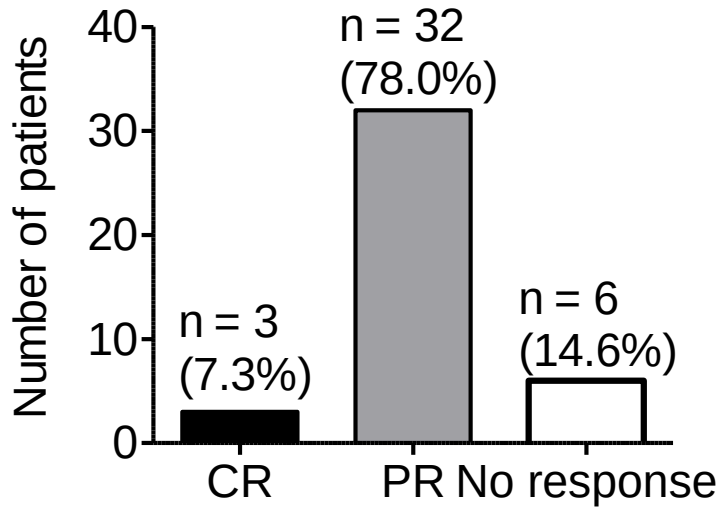


Zeiser R, Blazar B NEJM 2017

Ruxolitinib in chronic GVHD – initial clinical data







Zeiser R et al. Leukemia. 2015 Oct;29(10):2062-8

Ruxolitinib vs Best Available Therapy in Patients with Steroid-Refractory/Steroid-Dependent Chronic Graft-vs-Host Disease: Primary Findings from the Phase 3, Randomized REACH3 Study

Robert Zeiser,
on behalf of the REACH3 Study Group

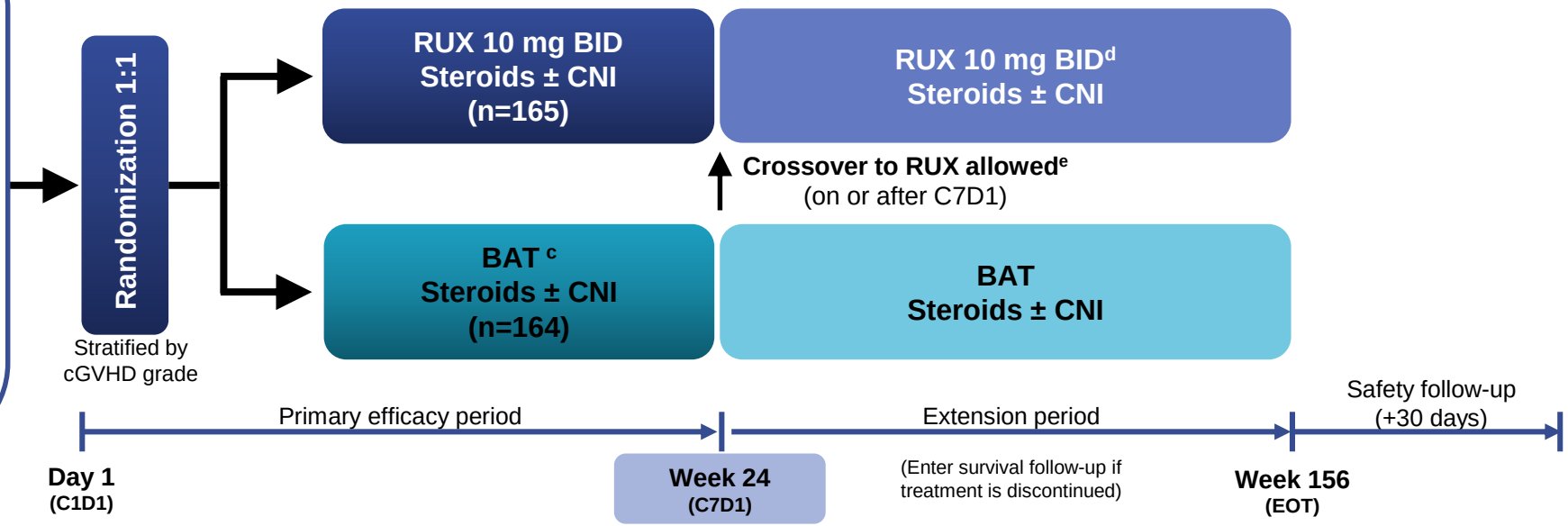
University Hospital Freiburg
Freiburg, Germany
Robert.Zeiser@uniklinik-freiburg.de

Presented at the 2020 ASH Annual Meeting & Exposition, held virtually on 5–8 December 2020

REACH3 (NCT03112603): a Phase 3, Randomized Study

Eligibility

- Age ≥ 12 years
- SR/D-cGVHD (moderate or severe), defined as:
  - Lack of response or disease progression after prednisone ≥1 mg/kg/day[a] for ≥1 week *or*
  - Disease progression with prednisone at >0.5 mg/kg/day or 1 mg/kg/every other day[a] for ≥4 weeks *or*
  - Increase to prednisone dose to >0.25 mg/kg/day[a] after 2 unsuccessful attempts to taper the dose
- Evident myeloid and platelet engraftment[b]



Primary endpoint: Overall response rate (ORR; complete response + partial response) at week 24

Key secondary endpoints:

- Failure-free survival (FFS)
- Modified Lee Symptom Scale (mLSS) response at week 24

BAT, best available therapy; BID, twice daily; C, cycle; CNI, calcineurin inhibitors; D, day; EOT, end of treatment period; FFS, failure-free survival; mLSS, modified Lee Symptom Score; NRM, non-relapse mortality; ORR, overall response rate; PR, partial response; RUX, ruxolitinib; SR/D, steroid-refractory or dependent. [a] Or prednisone equivalent. [b] Absolute neutrophil count > 1000/mm^3 and platelet count ≥ 25,000/mm^3. [c] Chosen by the investigator at randomization and could include extracorporeal photopheresis, low-dose methotrexate, mycophenolate mofetil, everolimus, sirolimus, infliximab, rituximab, pentostatin, imatinib, ibrutinib. [d] RUX tapering was permitted after day C7D1 for responding patients. [e] On or after C7D1, patients randomized to BAT who progressed, had a mixed or unchanged response, developed toxicity to BAT, or experienced a cGVHD flare could cross over from BAT to RUX.

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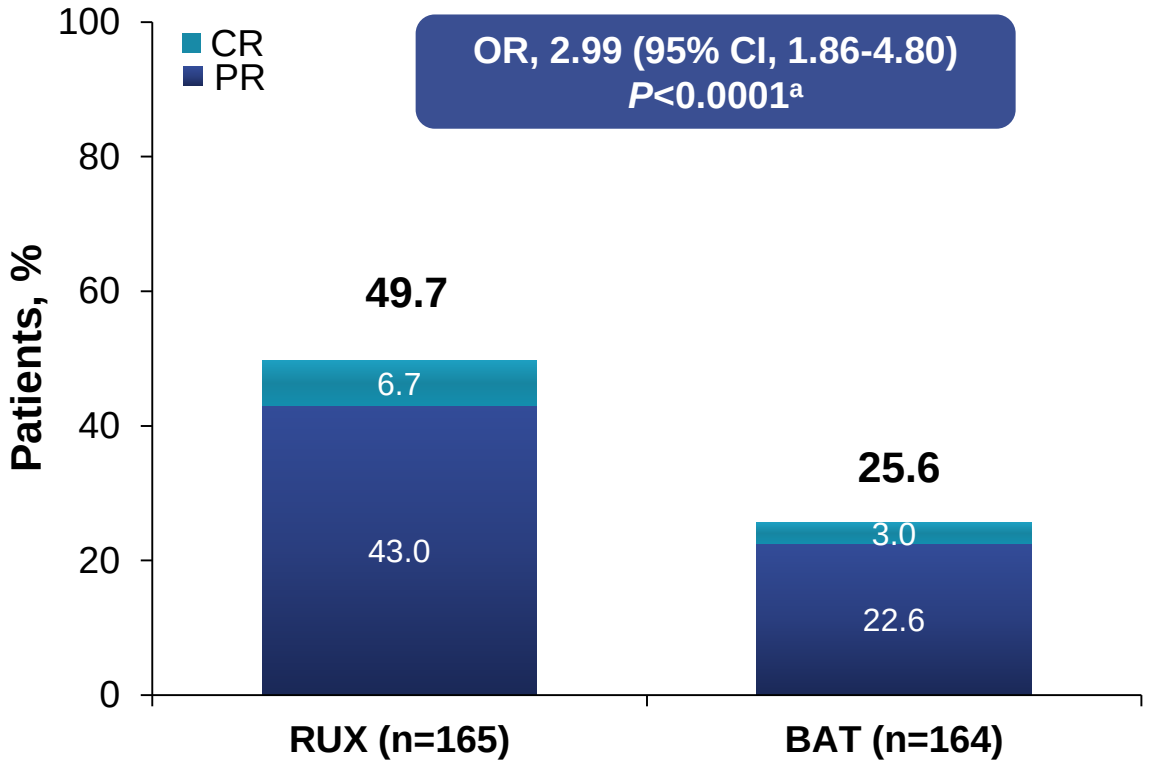
Overall Response Rate at Week 24

The primary endpoint was met: ORR was significantly higher with RUX



Characteristic	RUX (n=165)	BAT (n=164)
Responders, n (%)		
Complete response	**11 (6.7)**	**5 (3.0)**
Partial response	**71 (43.0)**	**37 (22.6)**
Nonresponders, n (%)		
Unchanged response	9 (5.5)	15 (9.1)
Mixed response	10 (6.1)	17 (10.4)
Progression	4 (2.4)	21 (12.8)
Other[b]	5 (3.0)	9 (5.5)
Unknown[c]	55 (33.3)	60 (36.6)

OR, odds ratio.

[a] Descriptive *P* value at primary analysis as the efficacy boundary was crossed at the interim analysis (N=196, ORR was 50.5% for RUX and 26.3% for BAT; *P*=0.0003). One-sided *P* value, odds ratio, and 95% CI were calculated using stratified Cochran-Mantel-Haenszel test with strata moderate vs severe cGVHD. [b] Other: patient with additional systemic therapies along with CR/PR per investigator assessment. [c] Considered nonresponders due to death, early discontinuation, or missing data.

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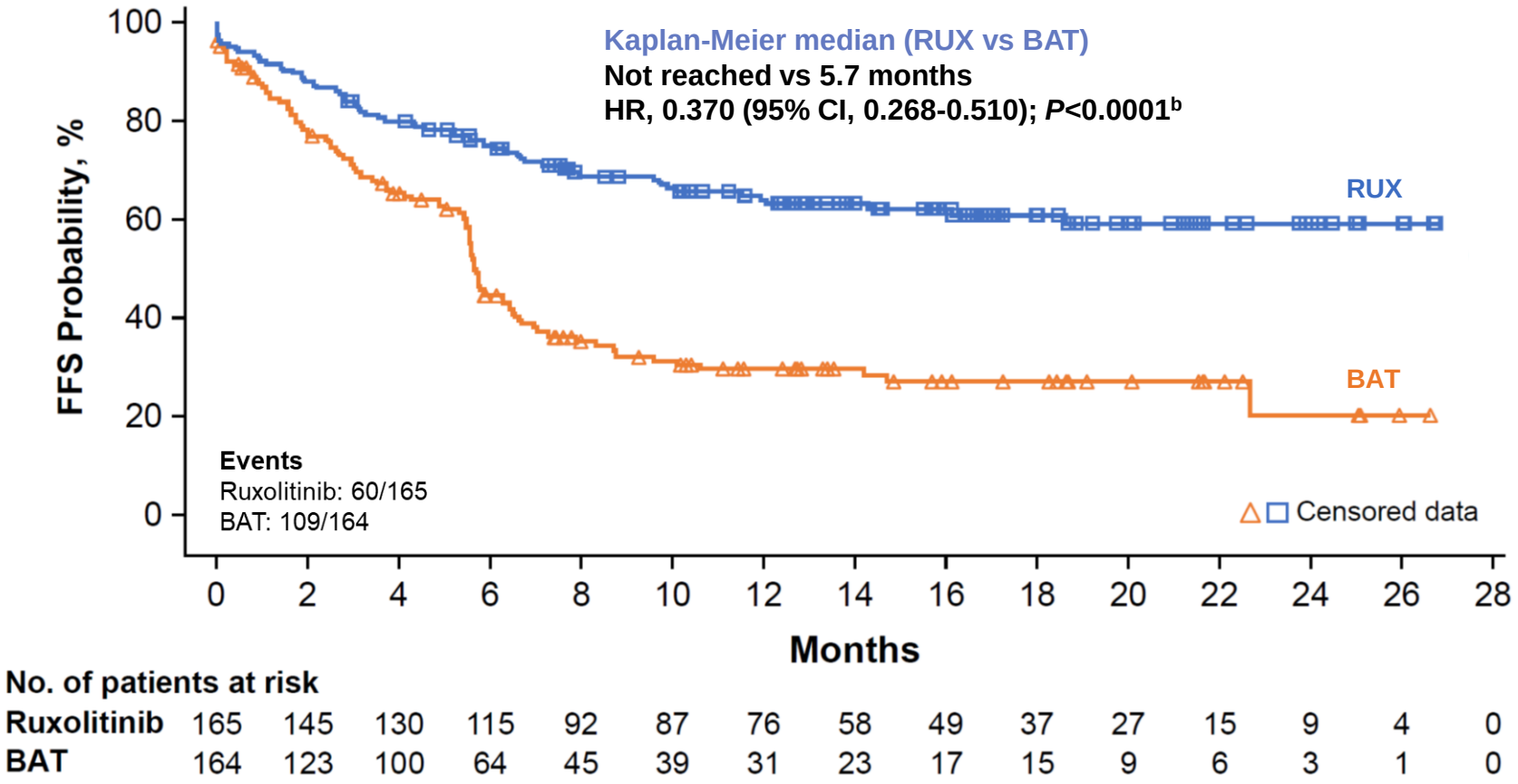
Failure-Free Survival at Week 24[a]

Median FFS was longer with RUX than with BAT



HR, hazard ratio.

[a] Defined as time to the earliest of recurrence of the underlying disease, the start of new systemic treatment for cGVHD, or death. [b] Descriptive *P* value at primary analysis (non-US testing sequence only) as the efficacy boundary was crossed at the interim analysis (N=196, hazard ratio, 0.315 [95% CI, 0.205-0.486], *P*<0.0001). For US testing sequence, the hypothesis was re-tested at the primary analysis following the overall hierarchical testing procedure.

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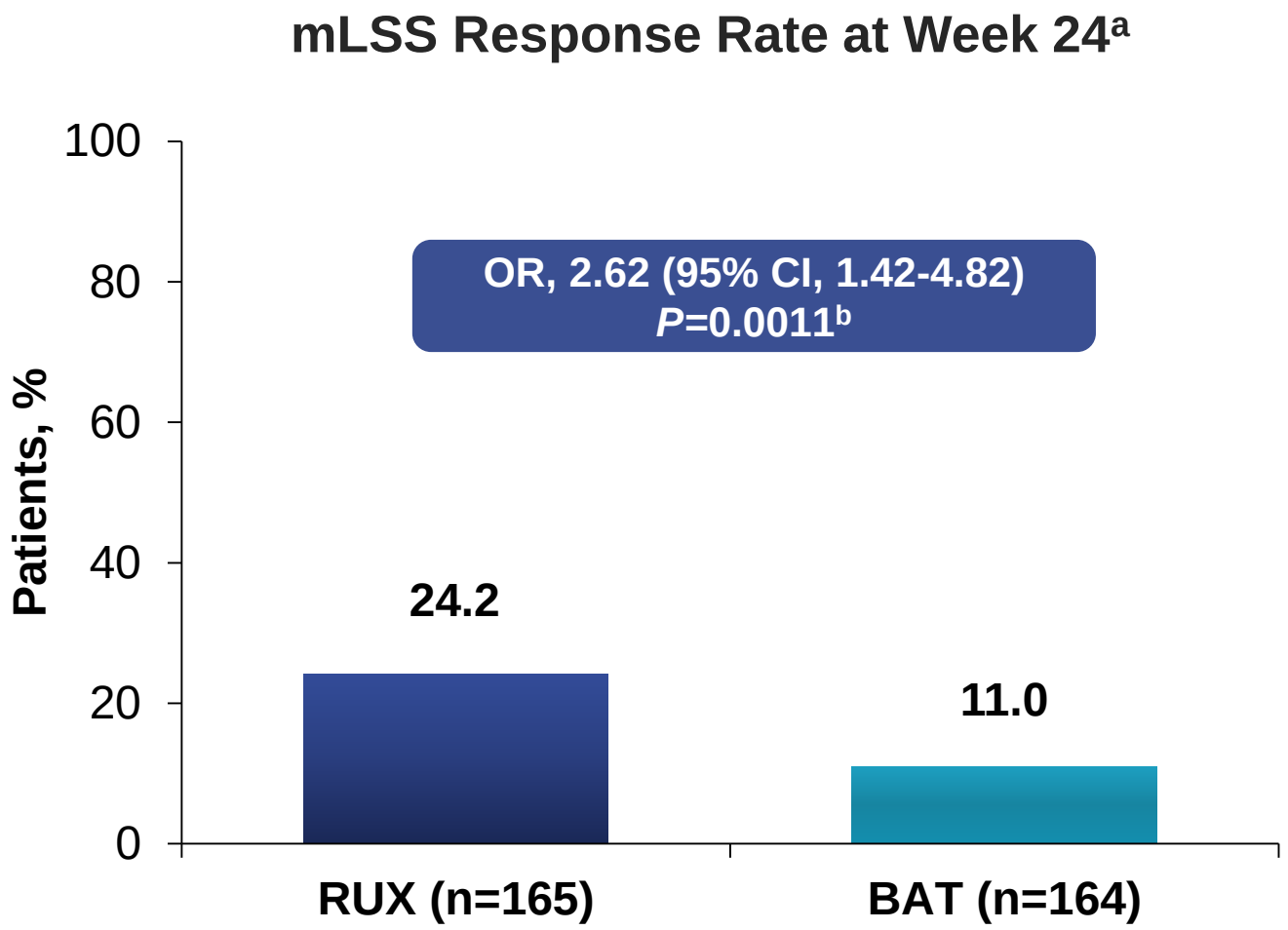
mLSS Response

Patients treated with RUX had greater improvements in symptoms



[a] mLSS response was defined as a ≥7-point reduction from baseline in the total symptom score. [b] Statistically significant at primary analysis. At interim analysis (N=196), patients receiving RUX had a numerically, but not significantly, higher mLSS responder rate (19.6% vs 8.1%; odds ratio, 2.80; *P*=0.0151) than those receiving BAT.

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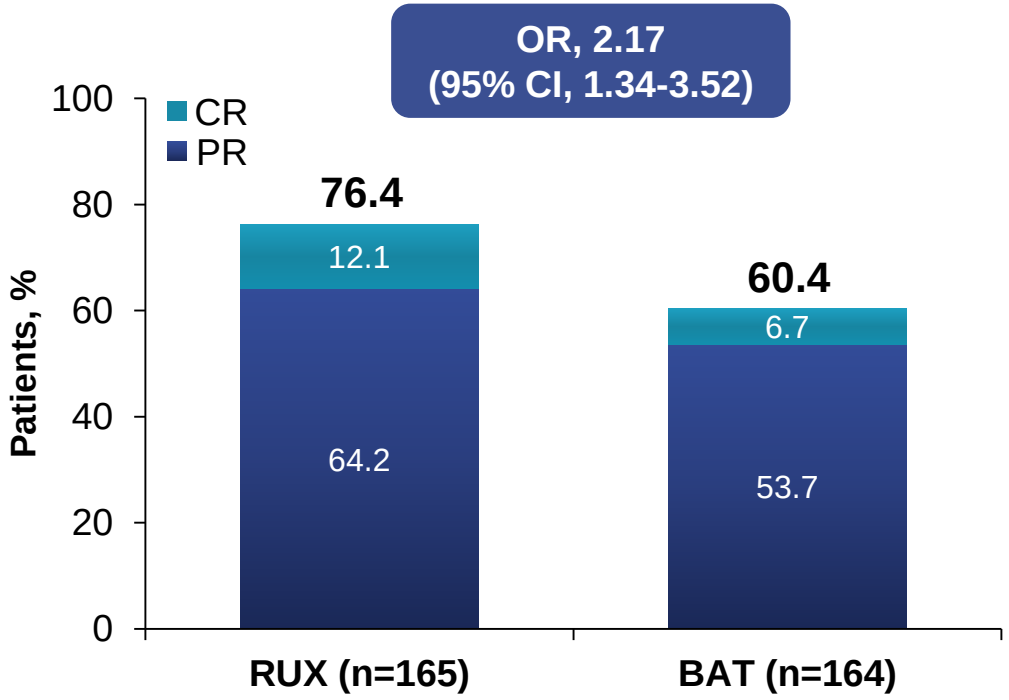
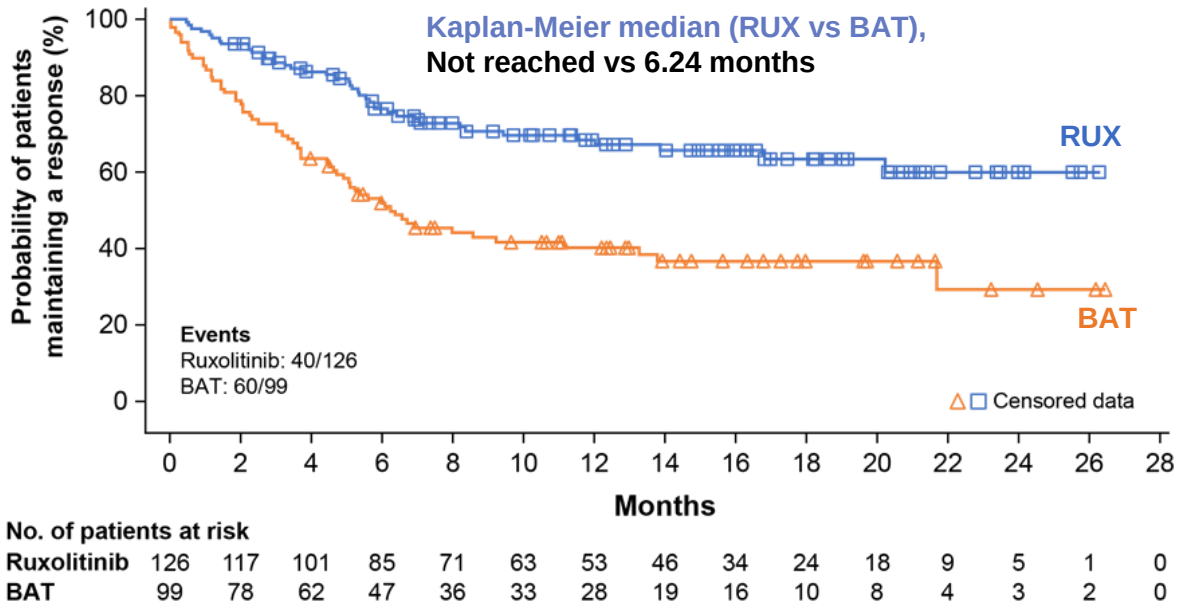
Best Overall Response[a]

Best overall response rate was higher with RUX than with BAT





- **Median duration of best overall response was 6.24 months in the BAT** arm but **was not reached in the RUX** arm

OR, odds ratio.

[a] Among patients who achieved a CR or PR at any time up to week 24. Duration of response from first documented PR or CR.

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Safety up to Week 24[a]

Rates of AEs were similar between treatment arms

	RUX (n=165)	BAT (n=158)
Duration of exposure up to study cutoff date, median (range), weeks[b]	41.3 (0.7-127.3)	24.1 (0.6-108.4)
Any-grade AEs, n (%)	161 (97.6)	145 (91.8)
Grade ≥ 3 AEs, n (%)	94 (57.0)	91 (57.6)
Serious AEs, n (%)	55 (33.3)	58 (36.7)
AEs leading to dose modification, n (%)	62 (37.6)	26 (16.5)
AEs leading to discontinuation, n (%)	27 (16.4)	11 (7.0)
Deaths, n (%)		
Up to data cutoff	**31 (18.8)**	**27 (16.5)**

AE, adverse event.

[a] Safety population: all patients who received ≥ 1 dose of study treatment. [b] Includes all systemic cGVHD treatments given during the main study period. [c] Most common causes of death were cGVHD (RUX, 22; BAT, 13) and infections (RUX, 2; BAT, 6).

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AEs (≥10%) up to Week 24

Cytopenias were the most common AEs in the RUX arm

Event, n (%)	RUX (n=165)[a]		BAT (n=158)[a]	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Hematologic				
Anemia	**48 (29.1)**	**21 (12.7)**	**20 (12.7)**	**12 (7.6)**
Thrombocytopenia[b]	**35 (21.2)**	**25 (15.2)**	**23 (14.6)**	**16 (10.1)**
Neutropenia	18 (10.9)	14 (8.5)	8 (5.1)	6 (3.8)
Gastrointestinal				
Diarrhea	17 (10.3)	1 (0.6)	21 (13.3)	2 (1.3)
Nausea	15 (9.1)	0	16 (10.1)	2 (1.3)
Infections				
Pneumonia	18 (10.9)	14 (8.5)	20 (12.7)	15 (9.5)
Laboratory abnormalities				
Alanine aminotransferase increased	25 (15.2)	7 (4.2)	7 (4.4)	0
Creatinine increased	23 (13.9)	0	7 (4.4)	1 (0.6)
Hypokalemia	13 (7.9)	3 (1.8)	16 (10.1)	7 (4.4)
Other				
Hypertension	26 (15.8)	8 (4.8)	20 (12.7)	11 (7.0)
Pyrexia	26 (15.8)	3 (1.8)	15 (9.5)	2 (1.3)
Cough	17 (10.3)	0	11 (7.0)	0
Fatigue	17 (10.3)	1 (0.6)	12 (7.6)	3 (1.9)

[a] Safety population: all patients who received ≥ 1 dose of study treatment. AEs were assessed according to the Common Terminology Criteria for Adverse Events v4.03. [b] Includes preferred terms “thrombocytopenia” and “platelet count decreased.”

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Conclusions

- This is the first successful, randomized phase 3 trial in adolescent and adult patients with cGVHD and inadequate response to steroids
- RUX demonstrated
  - **Significantly higher ORR** at week 24 than BAT (49.7% vs 25.6%; *P*<0.0001)
  - **Significant improvement in FFS** (HR, 0.370 [95% CI, 0.268-0.510]; *P*<0.0001)
  - **Significantly greater symptom improvement** (mLSS responder rate: 24.2% vs 11.0%; *P*=0.0011)
  - **Higher best overall response rate** up to week 24 than BAT (76.4% vs 60.4%)
- The safety profile of RUX was consistent with previous observations and with what is expected in patients with cGVHD
  - The most frequent AEs in the RUX arm were anemia and thrombocytopenia
- **RUX is the first agent to demonstrate superior efficacy to BAT in a phase 3 trial of patients with cGVHD and inadequate response to steroids**
- Findings from REACH3 support use of RUX as second-line therapy for cGVHD after initial steroid treatment

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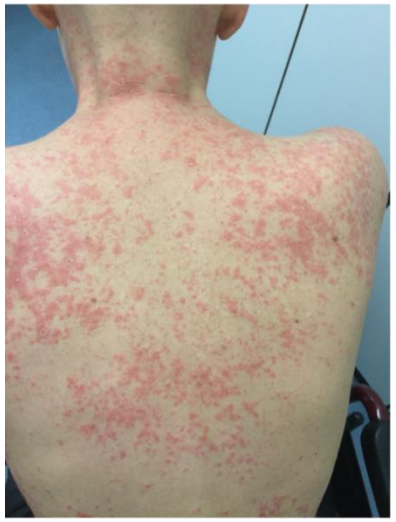
Future unmet medical needs?

Ruxolitinib refractory chronic GVHD?

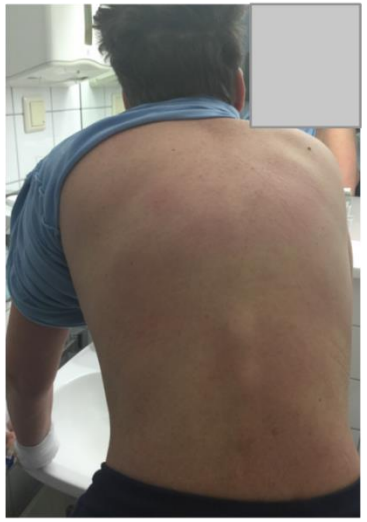
Ruxolitinib in combination with ECP

In patients with chronic GHVD that is refractory to ruxolitinib

Before



After Ruxo/ECP



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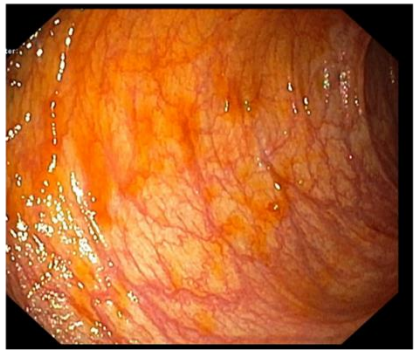

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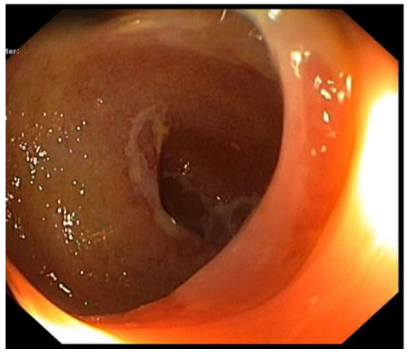

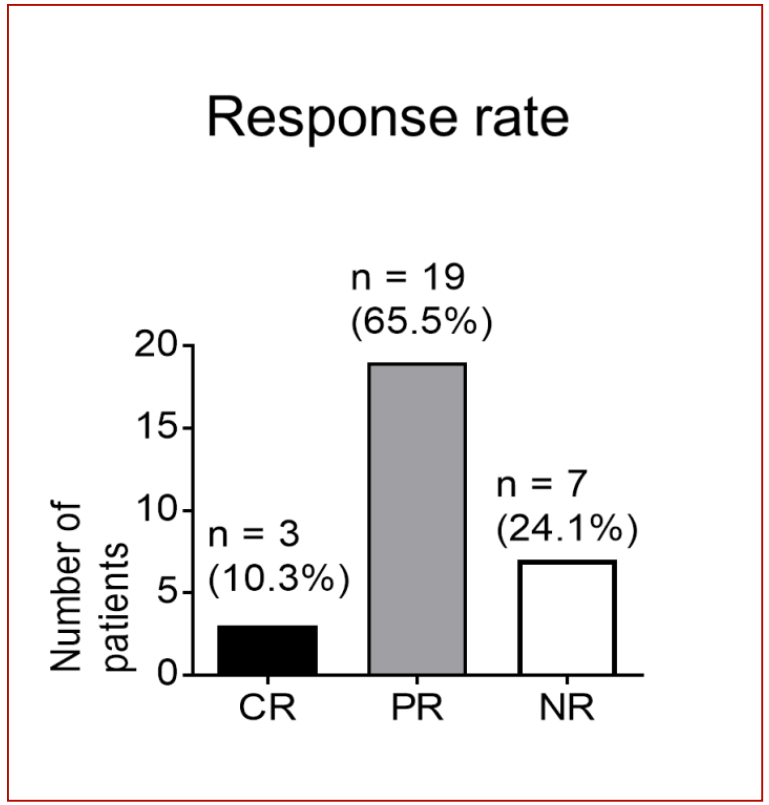

Q&A

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10.00-10.30	Prof. Dr. Robert Zeiser	**ruxolitinib** (JAK1/JAK2) Chronic GVHD, results from REACH3 and implications for therapy
	Q&A	
10.30-11.30	Steven Stein, MD	**ruxolitinib** (JAK1/JAK2) Long-term outcomes data in MF (EXPAND) and PV (RESPONSE-2)
	Peter Langmuir, MD	**parsaclisib** (PI3Kδ) CITADEL data, timelines and combination opportunities
		tafasitamab (CD19) L-MIND, firstMIND and development plans in DLBCL and beyond
	Q&A	

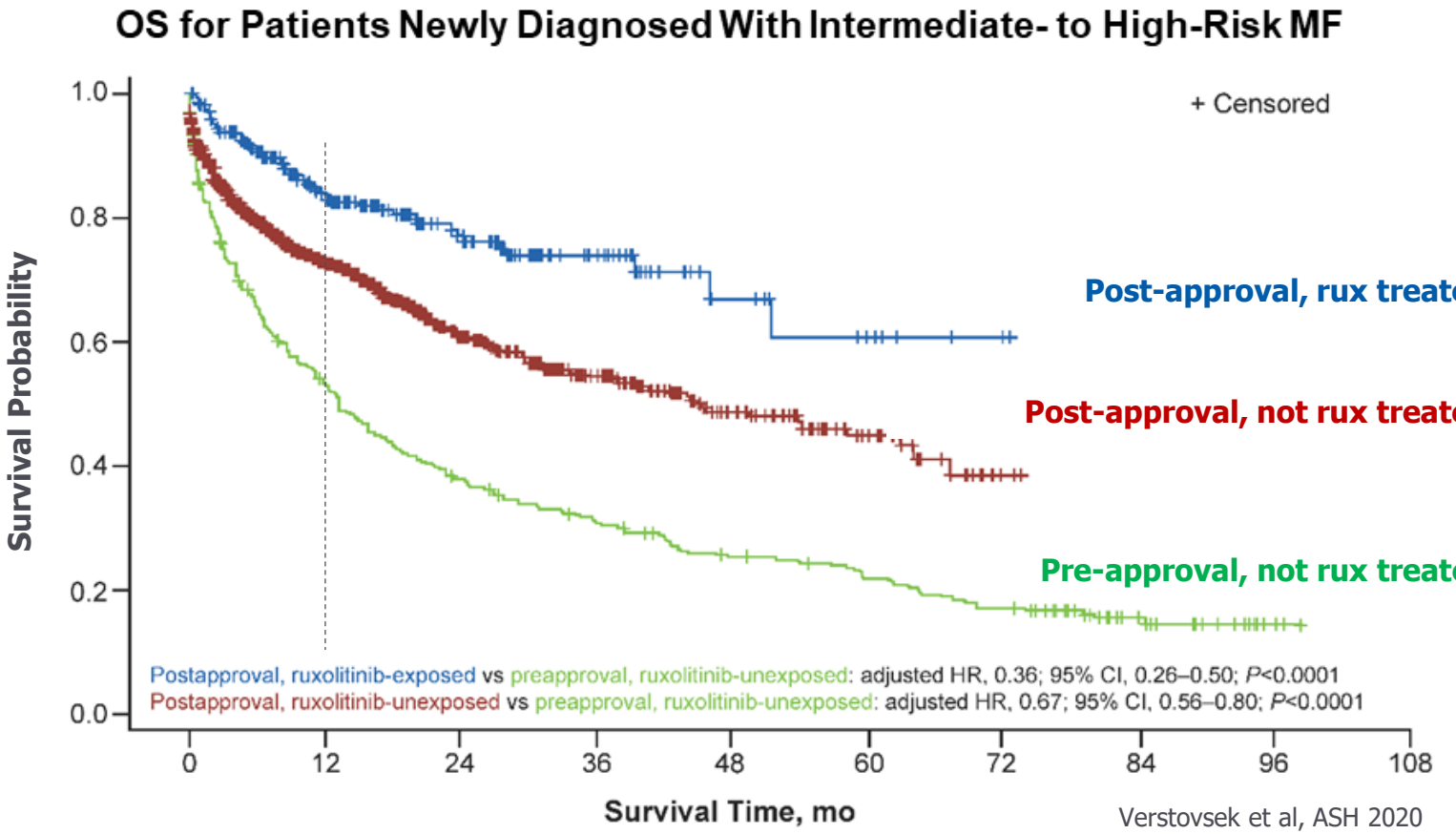
RUXOLITINIB

STEVEN STEIN, MD

CHIEF MEDICAL OFFICER

RUXOLITINIB HAS TRANSFORMED PATIENT OUTCOMES

INCREASED SURVIVAL IN U.S. MYELOFIBROSIS PATIENTS TREATED WITH RUXOLITINIB



Verstovsek et al, ASH 2020

1 year survival rates

Post-approval, rux treated	**82.3%**
Post-approval, not rux treated	**72.5%**
Pre-approval, not rux treated	**55.6%**

hazard ratio, 0.61

95% CI, 0.45–0.83

p=0.0016

Verstovsek et al, EHA 2020

Analysis conducted on 1,677 Medicare fee-for-service (FFS) beneficiaries who met inclusion criteria for assessment of intermediate- to high-risk MF

HR, hazard ratio; MF, myelofibrosis; OS, overall survival. One-year survival rate and risk of mortality were estimated using Kaplan-Meier and Cox proportional hazards regression analyses, adjusting for baseline demographic and clinical characteristics. OS was evaluated for 1-y periods, from the index date through the end of 1 y. Patients without a death date were censored at the end of 1 y or upon disenrollment, whichever occurred first.

Verstovsek et al, EHA 2020:
In the postapproval timeframe, patients in the ruxolitinib-exposed group had a significantly lower risk of mortality compared with the ruxolitinib-unexposed group (adjusted hazard ratio, 0.61; 95% CI, 0.45–0.83; P=0.0016)

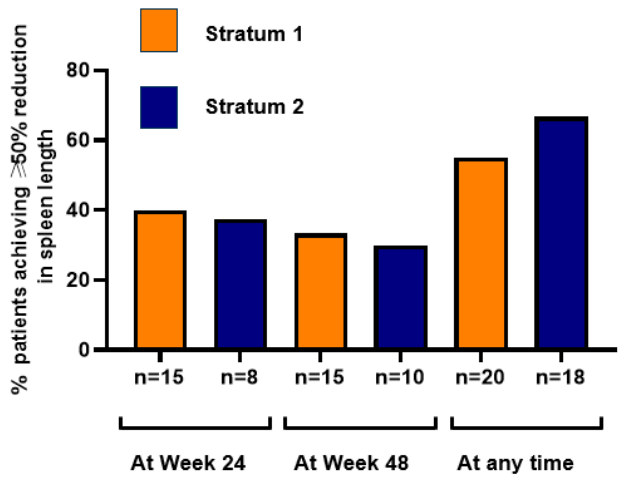
RUXOLITINIB IN PATIENTS WITH LOW PLATELETS

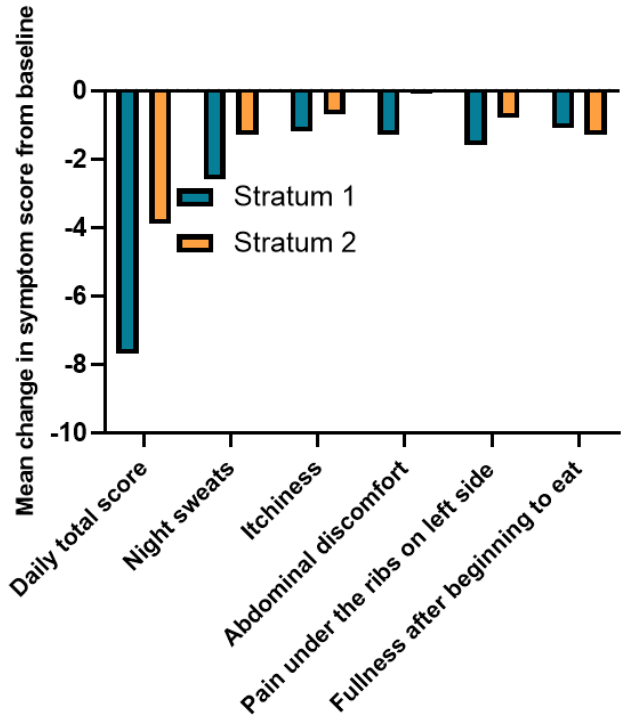
WELL-TOLERATED AND EFFICACIOUS IN A PREVIOUSLY UNSTUDIED MF POPULATION

- Based on baseline platelet counts
  - Stratum 1 (S1: 75 to 99 × 10^9/L)
  - Stratum 2 (S2: 50 to 74 × 10^9/L)

- Consistent with the known safety profile of ruxolitinib, and no new or unexpected safety signals were reported
- Starting dose of 10mg BID provided clinically meaningful reductions in spleen length and improvement in clinical symptoms

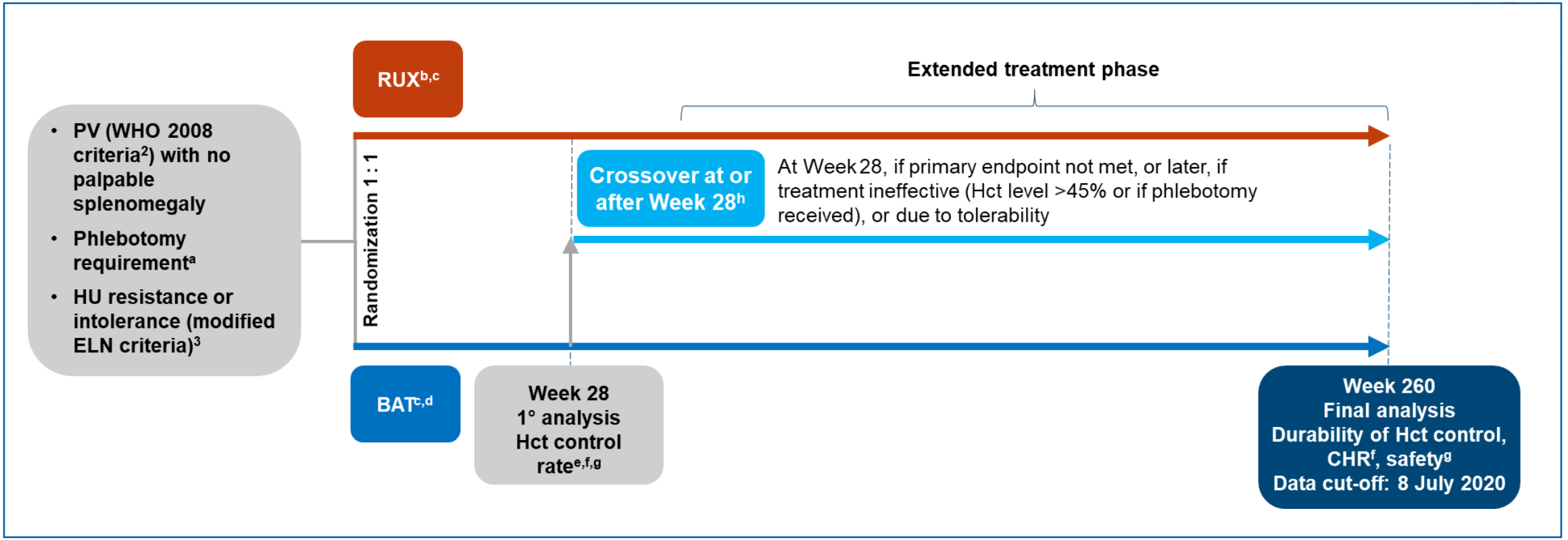
Guglielmelli et al, ASH 2020





RESPONSE-2: STUDY DESIGN OF FIVE YEAR TRIAL

PATIENTS WITH INADEQUATELY CONTROLLED PV – WITHOUT SPLENOMEGALY



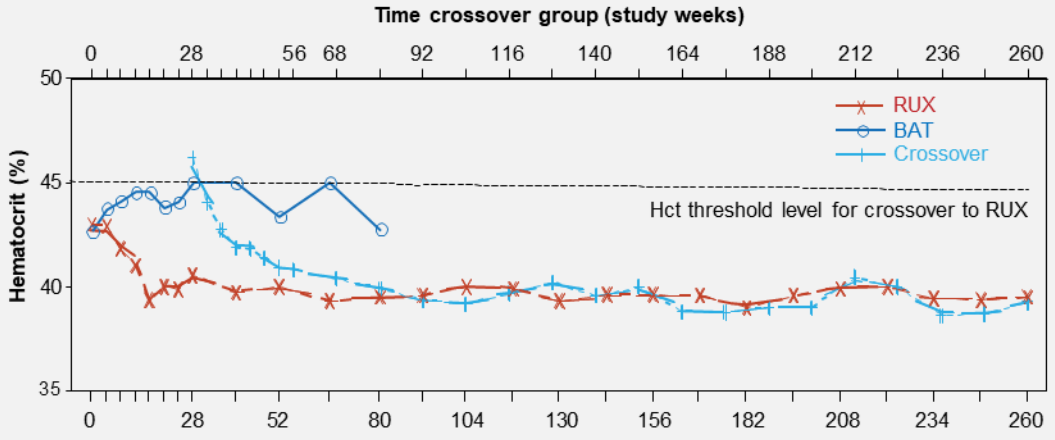
[a] Defined as Hct 40%-45% with ≥2 phlebotomies spaced ≥4 weeks apart within 24 weeks before screening ***or*** Hct >45% with ≥1 phlebotomy within 16 weeks before screening. [b] RUX-randomized patients had their doses individually titrated for efficacy and safety (max 25 mg bid). [c] All patients received low-dose aspirin unless medically contraindicated. [d] Investigator-selected BAT as monotherapy included HU (at a tolerated dose if patient likely to receive benefit), interferon/peg-interferon, anagrelide, pipobroman, immunomodulatory drugs, or no medication. [e] Hct control defined as absence of phlebotomy eligibility from Weeks 8 to 28, with only 1 post-randomization phlebotomy allowed prior to week 8; phlebotomy eligibility defined as confirmed Hct >45% and ≥3% higher than baseline, or >48%. [f] Key secondary endpoint was CHR, defined as the proportion of patients with Hct control, white blood cell count $<10\times10^9$/L, and platelet count $\leq400\times10^9$/L) at Week 28. [g] Additional endpoints included changes in patient-reported outcomes and *JAK2*^{V617F} allele burden over time. BAT, best available therapy; bid, twice daily; CHR, complete hematologic remission; ELN, European LeukemiaNet; Hct, hematocrit; HU, hydroxyurea; PV, polycythemia vera; RUX, ruxolitinib; WHO, World Health Organisation.

1. Passamonti F, et al. *Lancet Oncol*. 2017;18:88–99. 2. Thiele J, Kvasnicka HM. *Curr Hematol Malig Rep* 2009;4:33–40. 3. Barosi G, et al. *Blood*. 2013;121:4778–4781.

RESPONSE-2: FIVE YEAR RESULTS

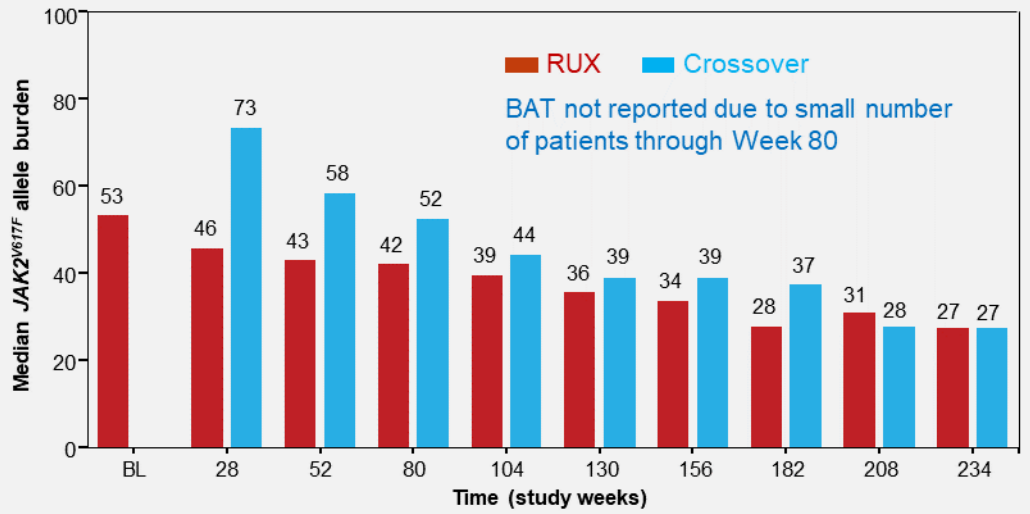
HCT CONTROL AND REDUCED ALLELE BURDEN IN BOTH RUX AND CROSSOVER PATIENTS

Median Hct levels (%) over time



N patients																					
RUX	73	67	66	65	67	65	63	61	64	61	63	63	60	61	58	58	58	55	54	56	52	40
BAT	74	71	70	67	24	16	11	6														
Crossover				58	54	52	53	49	50	48	48	47	48	46	41	30	29	37	38	39	35	33	22

Median *JAK2*^{V617F} allele burden over time



RUX	72	67	66	65	65	61	57	58	53	52
Crossover	-	57	49	40	44	44	44	38	35	37

Passamonti et al, ASH 2020

RESPONSE-2: FIVE YEAR RESULTS

FEWER PHLEBOTOMIES; SYMPTOM IMPROVEMENT; LOWER RATE OF THROMBOEMBOLIC EVENTS

~2x lower rate of phlebotomies (per patient per week) with early RUX vs delayed RUX initiation

	RUX (N=74)	BAT (N=75)	Crossover (N=58)
Total number of phlebotomies, n			
	60 (within 260 weeks)	106 (within 80 weeks)	99 (within 232 weeks)
Phlebotomy frequency category, n (%) of patients			
>0 – ≤2	12 (16.2)	29 (38.7)	23 (39.7)
>2 – ≤4	7 (9.5)	16 (21.3)	16 (27.6)
>4 – ≤6	4 (5.4)	2 (2.7)	2 (3.4)
>6 – ≤8	0 (0)	1 (1.3)	1 (1.7)

Significant improvement in PV symptoms (MPN-SAF TSS) with RUX vs BAT

- Proportion of patients with ≥50% reduction in MPN-SAF TSS from baseline at EOT:
  - RUX: 45.2% vs BAT[a]: 15.9%
  - Difference: 29.3% (95% CI 14.0, 44.6)
- Odds ratio ≥50% reduction MPN-SAF TSS (RUX/BAT):
  - 4.4 (95% CI 1.9, 10.1)

No new safety signals

- Exposure-adjusted TEE rate (any Grade)
  - ~2.5x lower with RUX vs BAT
  - ~2x lower with early RUX vs delayed RUX initiation

Passamonti et al, ASH 2020

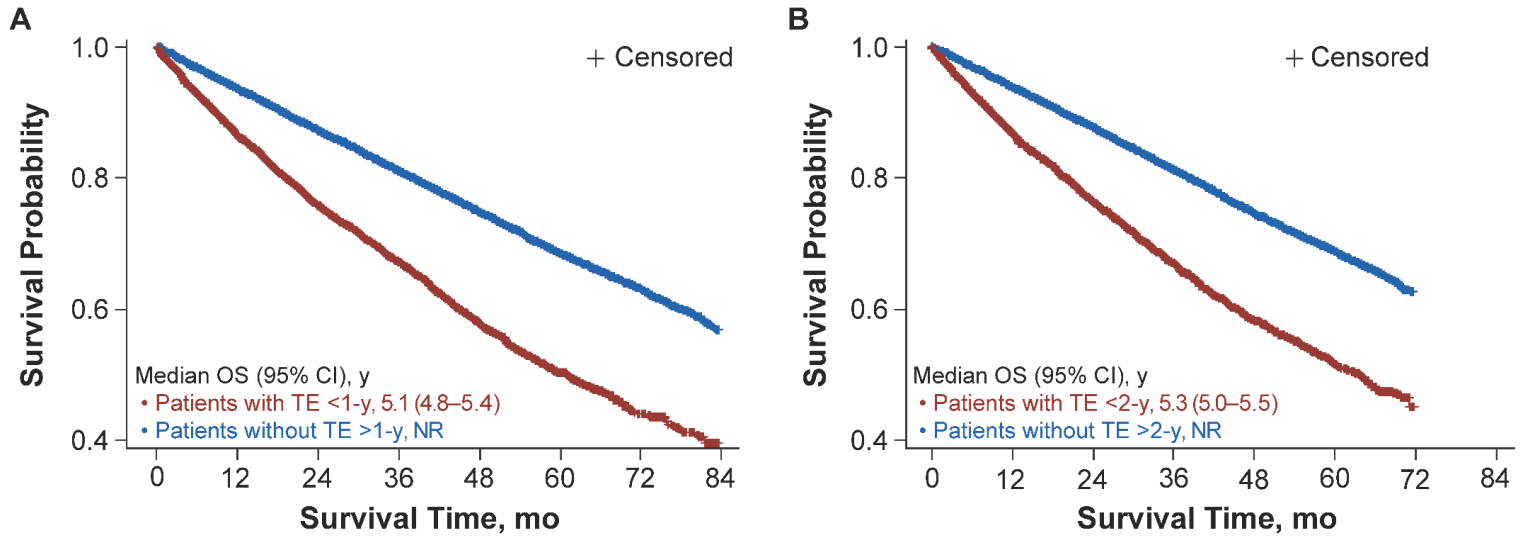
TEE = thromboembolic event

THE IMPORTANCE OF THERAPY IN POLYCYTHEMIA VERA

THROMBOSIS AND RISK OF MORTALITY IN NEWLY DIAGNOSED HIGH-RISK PATIENTS

- In 50,405 patients with PV, median time from diagnosis to first post-index thromboembolic event was 15.5 months
- The risk of mortality was increased for patients with PV who experienced a post-index TE compared with those who did not (adjusted HR,* 18.6; 95% CI, 16.1–21.6; *P*<0.001)

KM Curves for OS Among Patients with PV at (A) 1-y and (B) 2-y Landmarks Following Diagnosis†



Pemmaraju et al, ASH 2020

* HRs were estimated using Cox proportional hazard model with time dependent covariate analysis. Adjusted HR was obtained by adjusting for baseline patient characteristics.
† Patients were censored at the end of each 365-day landmark following diagnosis or upon death or discontinuation of follow-up, whichever occurred first.
HR, hazard ratio; NR, not reached; OS, overall survival; PV, polycythemia vera; TE, thrombotic event.

PARSACLISIB

PETER LANGMUIR, MD

GVP, ONCOLOGY TARGETED THERAPEUTICS

PARSACLISIB HAS A DIFFERENTIATED PROFILE

POTENT AND MORE SELECTIVE FOR THE DELTA ISOFORM THAN OTHER PI3Kδ INHIBITORS

Comparative potency and isoform selectivity of PI3Kδ inhibitors

	parsaclisib[1,2]	copanlisib[3,4]	idelalisib[5,6]	duvelisib[7]	umbralisib[8,9]	zandelisib[10]
PI3Kδ enzyme potency (IC_{50}, nM)	1	0.7	2.5	2.5	22	≤5
Fold selectivity:						
PI3Kα	>10,000	1	>300	640	>1,000	>1,000
PI3Kβ	>10,000	5	>200	34	>50	>65
PI3Kγ	>10,000	10	>35	11	>48	>500

IC_{50}, half-maximal inhibitory concentration

1. Phillips TJ, et al. ASH 2016. Poster 4195. 2. Shin et al., J Pharmacol Exp Ther 2020;374:211-222. 3. Liu N, et al. *Mol Cancer Ther*. 2013;12:2319-2330. 4. Aliqopa (Copanlisib) U.S. Prescribing Information, 2019. 5. Lanutti BJ, et al. *Blood*. 2011;117:591-594. 6. Zydelig (Idelalisib) U.S. Prescribing Information, 2018. 7. Fan L, et al. *Neoplasia*. 2020; 22(12): 714-724. 8. Burris HA, et al. ASCO 2016. Poster 7512. 9. Burris HA, et al. *Lancet Oncol*. 2018;19:486-496. 10. MEI Pharma, Inc, Corporate Presentation (ME-401: A Highly Differentiated PI3Kδ-Selective Inhibitor), June 2017; Accessed on November 10, 2020: https://www.meipharma.com/sites/default/files/me-401_presentation.pdf

THREE MONOTHERAPY DEVELOPMENT PROGRAMS

DATA FROM FOUR COHORTS PRESENTED AT ASH 2020

Data shared at ASH 2020

citadel-203

r/r follicular lymphoma
(≥2 prior systemic therapies)

citadel-204

r/r marginal zone lymphoma
(≥1 prior systemic therapy, BTK inhibitor–naïve)

citadel-205

r/r mantle cell lymphoma
(1–3 prior systemic therapies, BTK inhibitor–naïve) &
(1–3 prior systemic therapies including ibrutinib)

Parsaclisib 20 mg **once daily** for 8 weeks followed by 20 mg **once weekly**

-or-

Parsaclisib 20 mg **once daily** for 8 weeks followed by 2.5 mg **once daily**, continuously

During the studies, **continuous daily** dosing was selected as preferred regimen. Weekly dosing patients were allowed to switch to continuous daily dosing.

Incyte

ADVERSE EVENTS IN THE CITADEL TRIALS

PARSACLISIB SHOWED ACCEPTABLE SAFETY PROFILE AND WAS GENERALLY WELL TOLERATED

Patients with any serious TEAE; n (%)

	All treated	Daily dosing
CITADEL-203 (FL)	53 (42)	43 (42)
CITADEL-204 (MZL, BTK-naïve)	43 (43)	36 (50)
CITADEL-205 (MCL, BTK-naïve)	42 (39)	33 (43)
CITADEL-205 (MCL, post ibrutinib)	23 (43)	18 (44)

Serious TEAEs of special interest[1]

- Diarrhea: ~10%; colitis: <10%
- Median time to grade ≥3 diarrhea / colitis events: ~4-7 months
- Median time to improvement of diarrhea: ~1-4 weeks[2]

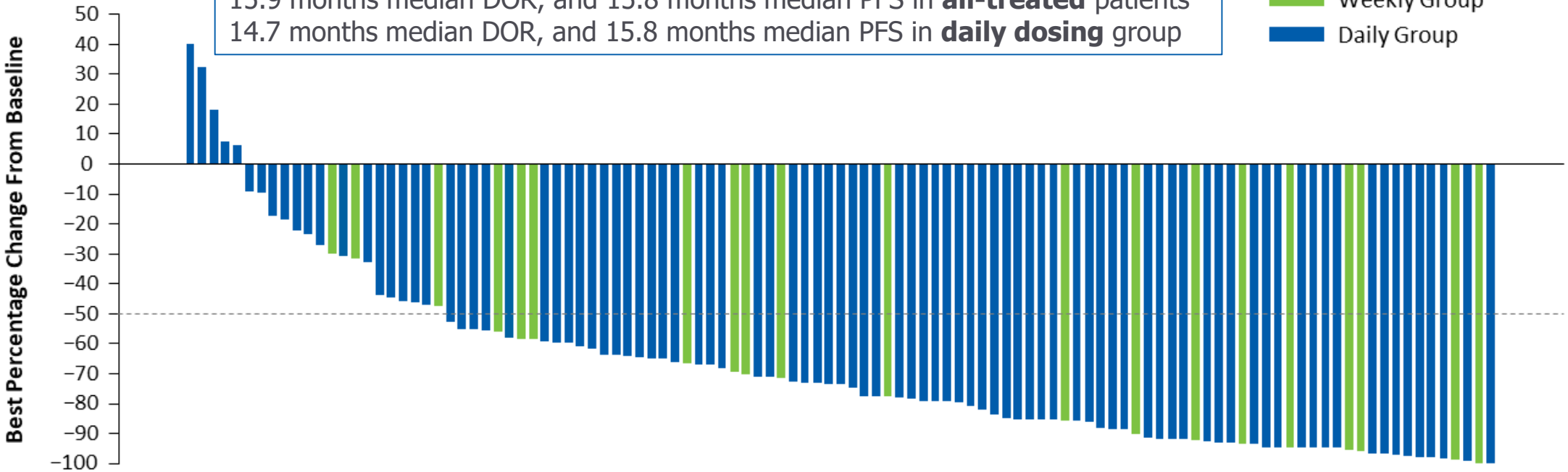
Dose modifications due to TEAEs (any grade)[1]

- Interruption ~30-55%
- Reduction ~5-15%
- Discontinuation ~5-30%

1. Summary safety data from CITADEL-203, CITADEL-204 and CITADEL-205 trials as presented at ASH 2020
2. Summary data exclude post ibrutinib cohort of CITADEL-205 wherein median time to improvement was 67 days (9.6 weeks) based on 3 events of grade ≥3 diarrhea

FOLLICULAR LYMPHOMA

75% ORR BY INDEPENDENT REVIEW COMMITTEE IN DAILY DOSING GROUP



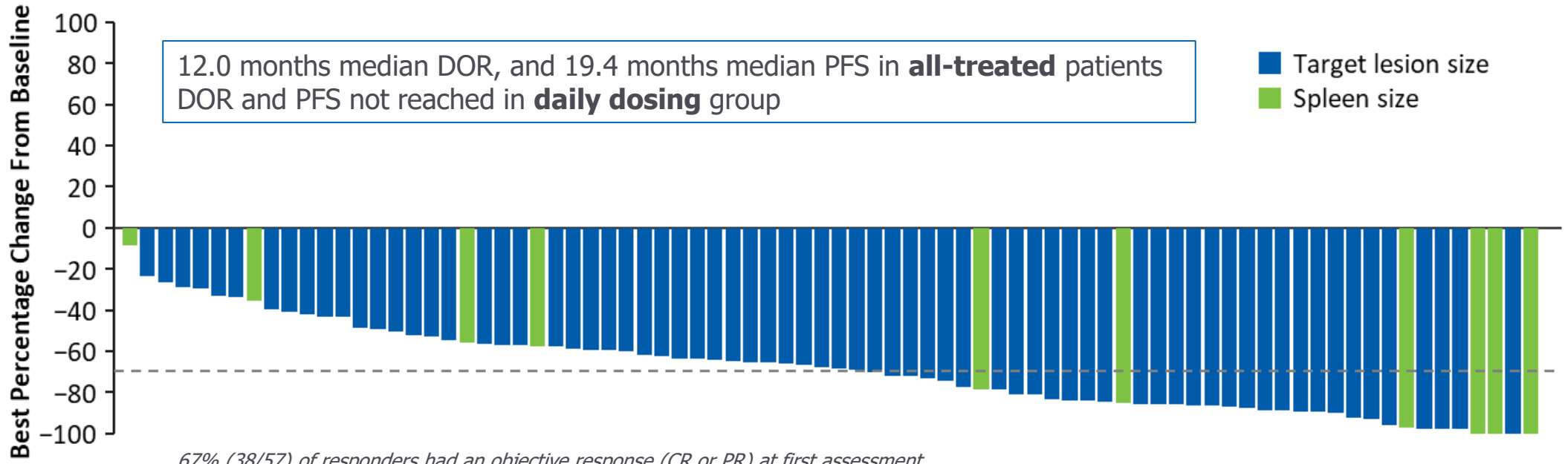
90% (106/118) of efficacy evaluable patients overall and 91% (86/95) of efficacy evaluable patients in the Daily Group had tumor regression at target lesions

Lynch et al, ASH 2020

ORR = overall response rate; DOR = duration of response; PFS = progression-free survival

MARGINAL ZONE LYMPHOMA: BTKi-NAÏVE

57% ORR BY INDEPENDENT REVIEW COMMITTEE IN DAILY DOSING GROUP*



67% (38/57) of responders had an objective response (CR or PR) at first assessment
Median time to first response was 8.1 weeks

Comparable efficacy was observed in patients with nodal, extranodal, and splenic marginal zone lymphoma

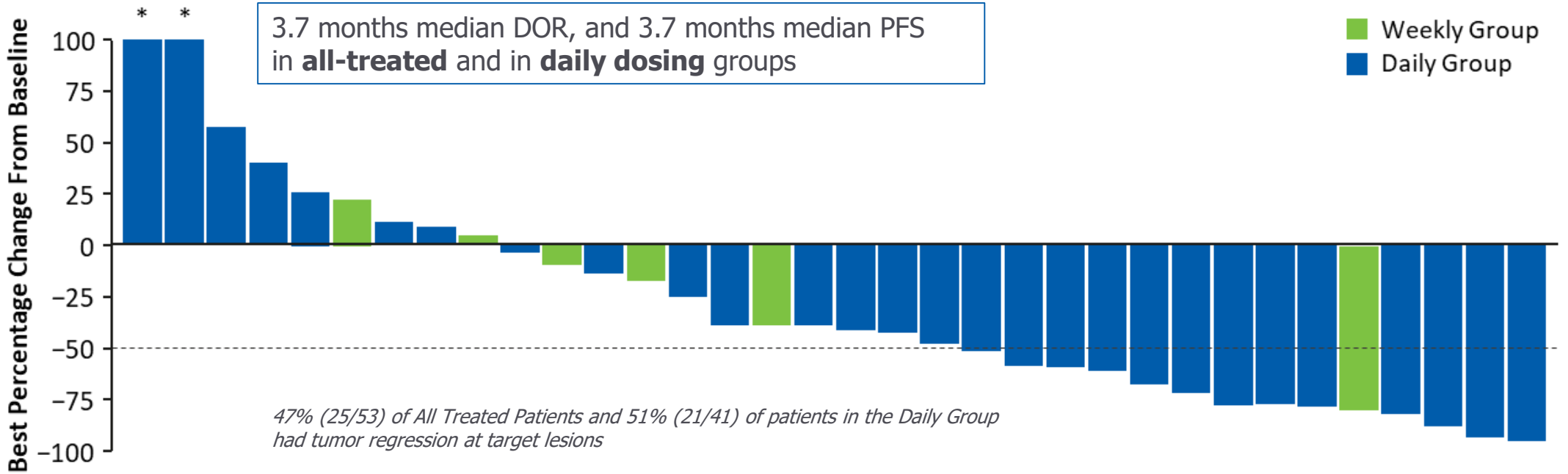
Phillips et al, ASH 2020

ORR = overall response rate; DOR = duration of response; PFS = progression-free survival

* For patients with measurable lesions at baseline, target lesion size as measured by sum of product of diameters of all target lesions was used to assess disease burden.
For splenic MZL patients who have splenomegaly only at baseline, the spleen size as measured by the enlarged portion of the splenic length (ie, splenic length in excess of the 13 cm normal threshold) was used to assess disease burden.

MANTLE CELL LYMPHOMA: IBRUTINIB-EXPERIENCED

29% ORR BY INDEPENDENT REVIEW COMMITTEE IN DAILY DOSING GROUP



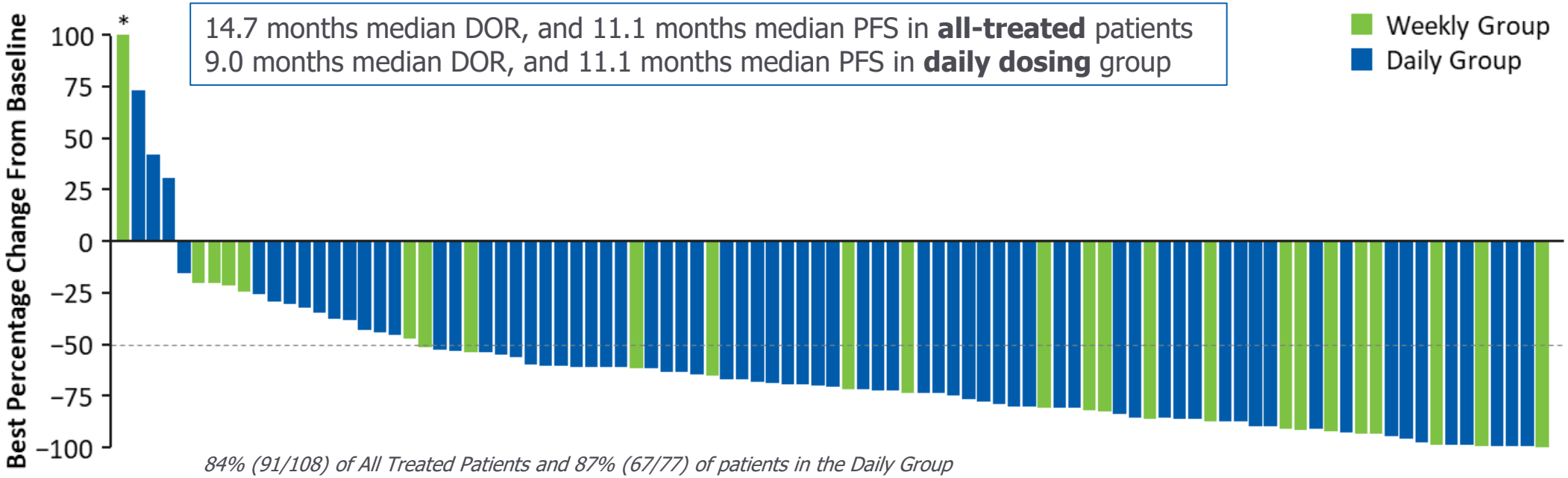
* Patients had best percentage change from baseline >100%.

Zinzani et al, ASH 2020

ORR = overall response rate; DOR = duration of response; PFS = progression-free survival

MANTLE CELL LYMPHOMA: BTKi-NAÏVE

71% ORR BY INDEPENDENT REVIEW COMMITTEE IN DAILY DOSING GROUP



* Patient had best percentage change from baseline >100%.

Mehta et al, ASH 2020

ORR = overall response rate; DOR = duration of response; PFS = progression-free survival

COMPELLING EFFICACY DATA

EXCITING OPPORTUNITIES TO BRING NEW THERAPEUTIC OPTIONS TO R/R NHL PATIENTS

	Data shared at ASH 2020	Continuous daily dosing group
citadel-203	**r/r follicular lymphoma** (≥2 prior systemic therapies)	**ORR: 75%, DOR: 14.7 months, PFS: 15.8 months**
citadel-204	**r/r marginal zone lymphoma** (≥1 prior systemic therapy, BTK inhibitor–naïve)	**ORR: 57%, median DOR & PFS not reached**
citadel-205	**r/r mantle cell lymphoma** (1–3 prior systemic therapies, BTK inhibitor–naïve) & (1–3 prior systemic therapies including ibrutinib)	**ORR: 71%, DOR: 9.0 months, PFS: 11.1 months** BTKi-naïve cohort

ORR = overall response rate; DOR = median duration of response; PFS = median progression-free survival

TIMELINES AND NEXT STEPS

EXCITING OPPORTUNITIES TO BRING NEW THERAPEUTIC OPTIONS TO R/R NHL PATIENTS

Data shared at ASH 2020

citadel-203

r/r follicular lymphoma
(≥2 prior systemic therapies)

citadel-204

r/r marginal zone lymphoma
(≥1 prior systemic therapy, BTK inhibitor–naïve)

citadel-205

r/r mantle cell lymphoma
(1–3 prior systemic therapies, BTK inhibitor–naïve) &
(1–3 prior systemic therapies including ibrutinib)

- Follow-up ongoing; 12 months after last responder recommended by FDA
- NDA expected H2 2021

➢ **Significant opportunities in r/r NHL**

- Follicular: ~9,000 new patients per year
- Marginal zone; ~5,000 new patients per year
- Mantle cell: ~5,000 new patients per year

Epidemiology assumptions for 3L drug treated FL, and 2L drug treated MZL and MCL for US, Europe and Japan

DRG- Market Forecast Assumptions NHL 2018-2028 for Y2020; Teras et al. 2016 US Lymphoid Malignancy Statistics by World Health Organization Subtypes. CA CANCER J CLIN 2016;66:443–459; Heilgeist et al. Cancer. Prognostic Value of the Follicular Lymphoma International Prognostic Index Score in Marginal Zone Lymphoma: An Analysis of Clinical Presentation and Outcome in 144 Patients. Cancer. 2013 Jan 1;119(1):99-106. doi: 10.1002/cncr.27704. Epub 2012 Jun 26; SEER cancer stats; GLOBOCAN; European Cancer Information System (ECIS; Smith et al. Lymphoma incidence, survival and prevalence 2004–2014: sub-type analyses from the UK's Haematological Malignancy Research Network. Br J Cancer. 2015 Apr 28; 112(9): 1575–1584; Marcos-Gragera et al. Br J Haematol. 2015 Nov;171(3):366-72.016;66:443–459; Carbone et al. Follicular Lymphoma. Nat Rev Dis Primers. 2019 Dec 12;5(1):83. doi: 10.1038/s41572-019-0132-x; Leonard et al. AUGMENT: A Phase III Study of Lenalidomide Plus Rituximab Versus Placebo Plus Rituximab in Relapsed or Refractory Indolent Lymphoma J Clin Oncol. 2019 May 10; 37(14): 1188–1199. doi: 10.1200/JCO.19.00010; Jain et al. Mantle cell lymphoma: 2019 update on the diagnosis, pathogenesis, prognostication, and management. Am J Hematol. 2019 Jun;94(6):710-725. Am J Hematol. doi: 10.1002/ajh.25487. Epub 2019 Apr 19.; Nakaruma et al. Marginal zone B-cell lymphoma: lessons from Western and Eastern diagnostic approaches. Pathology. 2020 Jan;52(1):15-29. doi: 10.1016/j.pathol.2019.08.012. Epub 2019 Nov 19.

PARSACLISIB BROAD DEVELOPMENT STRATEGY

OPPORTUNITIES AS BOTH MONOTHERAPY AND IN COMBINATION

Monotherapy

- Follicular lymphoma
- Marginal zone lymphoma
- Mantle cell lymphoma

→ **Data at ASH; NDA expected H2 2021**

- Autoimmune hemolytic anemia → **Proof-of-concept trial underway**

Combinations

ruxolitinib

- 1L myelofibrosis (MF)
- MF inadequate responders

→ **Phase 3s underway within LIMBER program**

tafasitamab[1]

- r/r B-cell malignancies → **Proof-of-concept trial to start 2021**

1. Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys.

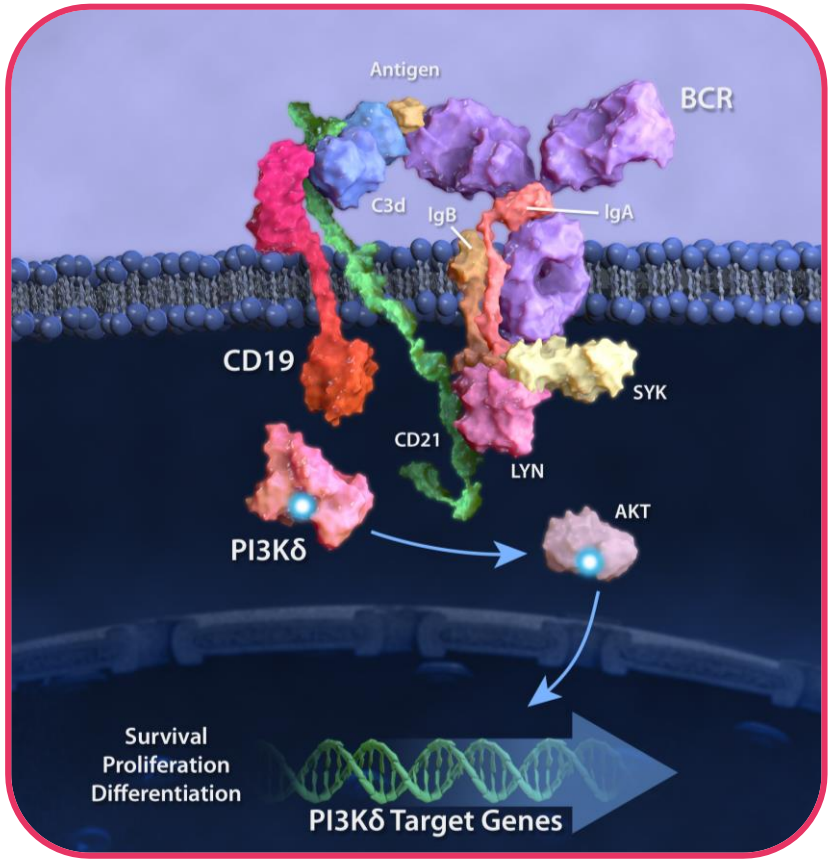
TAFASITAMAB

PETER LANGMUIR, MD

GVP, ONCOLOGY TARGETED THERAPEUTICS

OPPORTUNITY FOR CD19 AND PI3Kδ COMBINATION

POTENTIAL FOR INCREASED ANTITUMOR ACTIVITY WITH TAFASITAMAB + PARSACLISIB



COSMOS Cohort A (n=11)[1]
tafasitamab + idelalisib
r/r CLL patients post BTKi

Efficacy
ORR of 91% (10/11)

Safety
Grade ≥3 TEAE (n):
- neutropenia (5)
- anemia (3)
- thrombocytopenia (3)

Trial to start in 2021
tafasitamab + parsaclisib

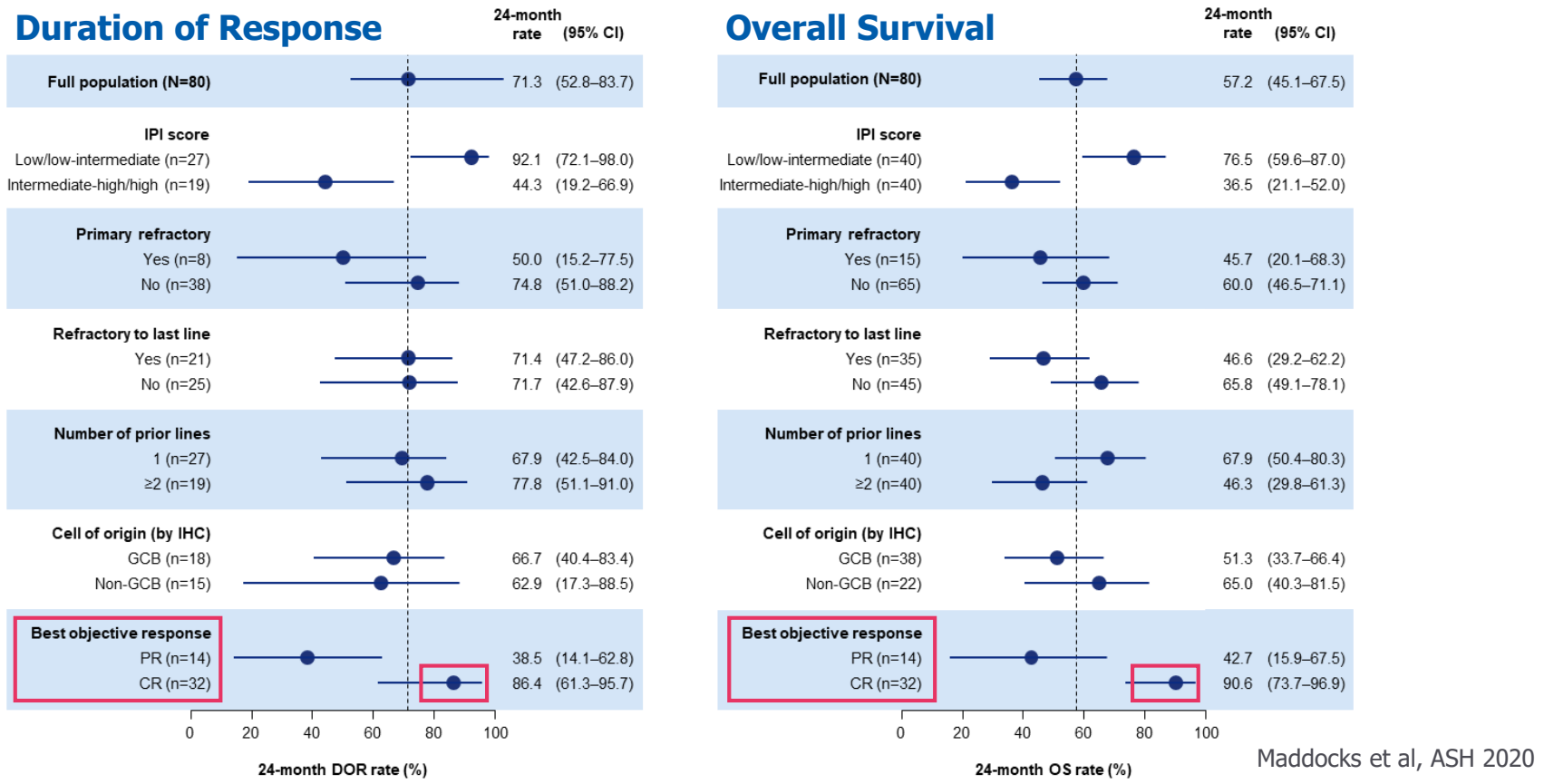
Key inclusion criteria
- r/r B-cell malignancies
- ≥1 prior anti-CD20 therapy

1. Staber et al, ASH 2019

Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys. Monjuvi (tafasitamab-cxix) is a CD19-directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).

L-MIND DATA BY SUBGROUP AFTER ≥ 2 YEARS

PATIENTS WITH COMPLETE RESPONSES EXPERIENCE LONG DoR AND HIGH OVERALL SURVIVAL

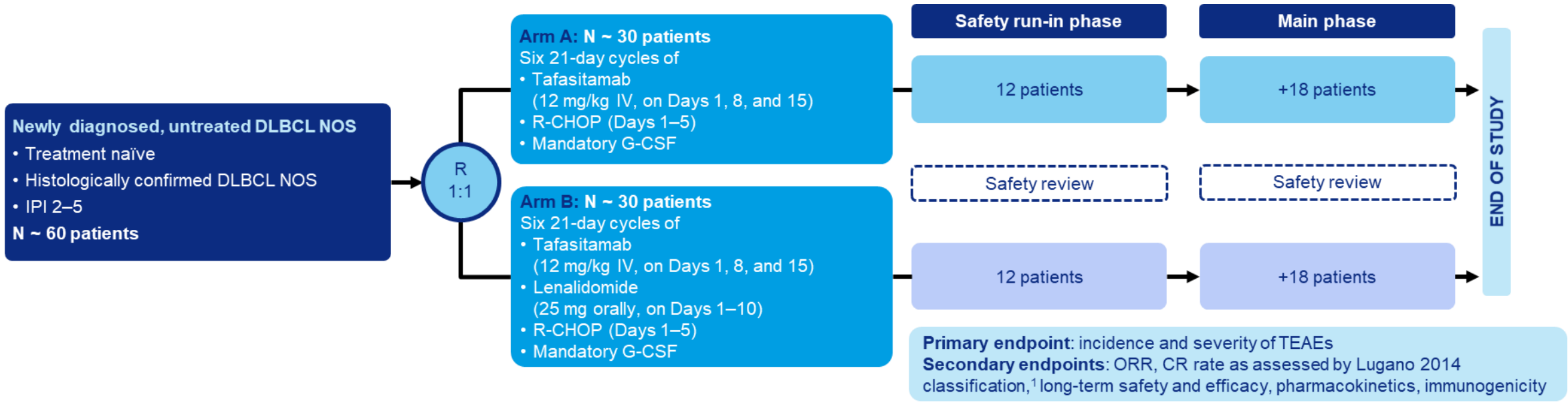


Maddocks et al, ASH 2020

Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys. Monjuvi (tafasitamab-cxix) is a CD19-directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).

firstMIND: STUDY DESIGN

TAFASITAMAB +/- LENALIDOMIDE IN ADDITION TO R-CHOP IN NEWLY-DIAGNOSED DLBCL



In the lenalidomide arm, prophylaxis with either low-molecular weight heparins or aspirin was recommended.

Belada et al, ASH 2020

1. Cheson BD, et al. J Clin Oncol 2014;32:3059–68.

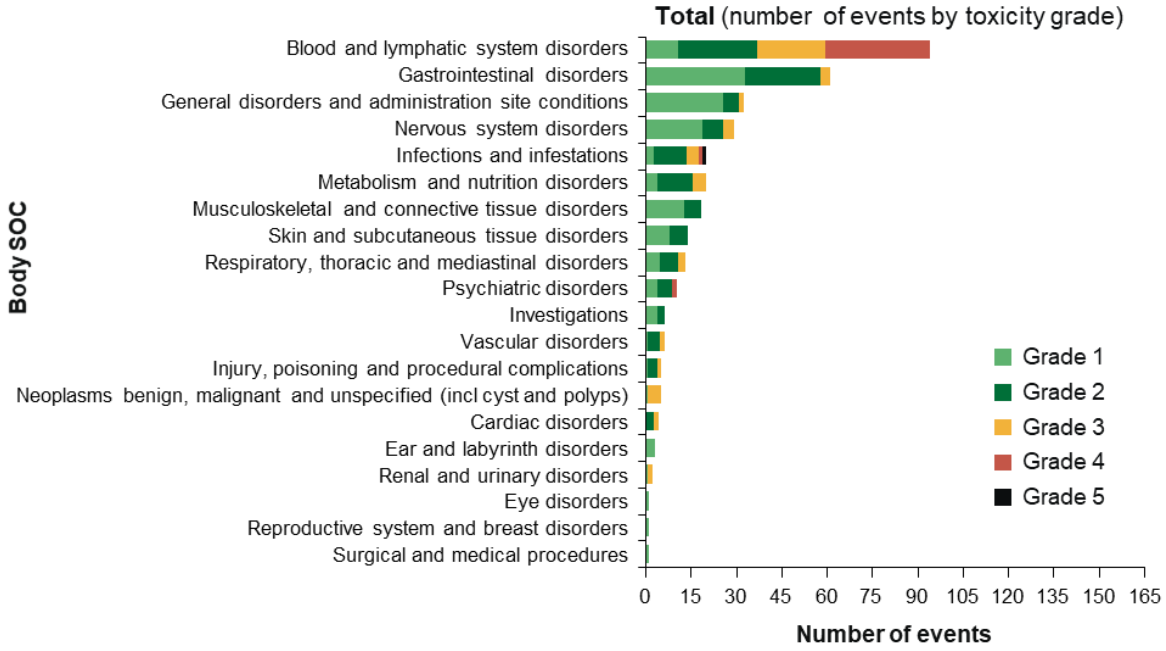
DLBCL, diffuse large B-cell lymphoma; G-CSF, granulocyte-colony stimulating factor; IPI, international prognostic index; IV, intravenous; NOS, not otherwise specified; R, randomized; R-CHOP, rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine, prednisolone.

Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys. Monjuvi (tafasitamab-cxix) is a CD19-directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).

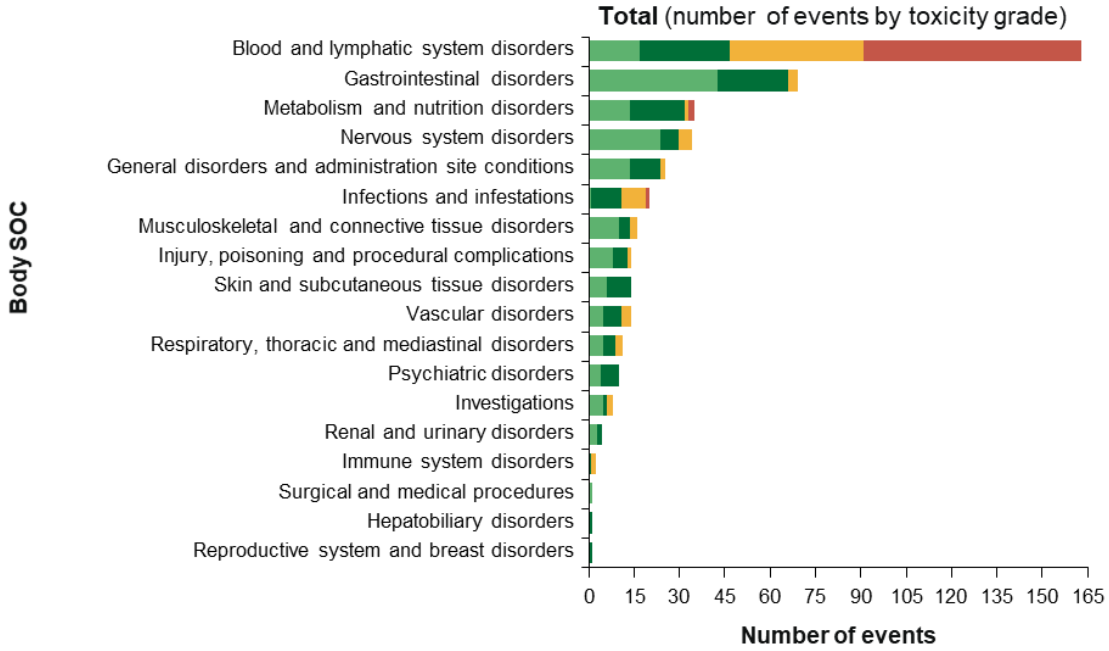
firstMIND: PRELIMINARY SAFETY RESULTS

NO NEW SAFETY SIGNALS OBSERVED IN COMBINATION WITH R-CHOP OR WITH R^2-CHOP

Arm A: Tafasitamab + R-CHOP (n=33)



Arm B: Tafasitamab + lenalidomide + R-CHOP (n=33)



Belada et al, ASH 2020

SOC, system organ class

Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys. Monjuvi (tafasitamab-cxix) is a CD19-directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).

TAFASITAMAB: GLOBAL CLINICAL DEVELOPMENT

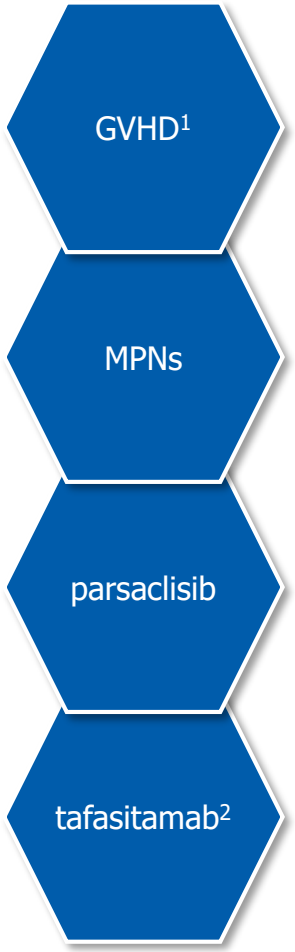
	Study	Arms	Status
r/r DLBCL	L-MIND (~80 pts)	+ lenalidomide	FDA approved in 2L+ DLBCL → Primary endpoint: ORR (2-year analysis presented at EHA 2020)
r/r DLBCL	B-MIND (~450 pts)	+ bendamustine vs bendamustine + rituximab	Ongoing, data expected 2022 → Primary endpoint: PFS (IDMC futility passed November 2019)
1L DLBCL	firstMIND (66 pts)	+/- lenalidomide + R-CHOP	Initial data presented ASH 2020 ✓
1L DLBCL	frontMIND (~900 pts)	+ lenalidomide + R-CHOP vs R-CHOP	**Trial expected to start in 2021** → Primary endpoint: PFS
Other r/r NHL	inMIND; follicular lymphoma (~500 pts)	+ lenalidomide + rituximab (R^2) vs R^2	**Trial expected to start in 2021** → Primary endpoint: PFS
Other r/r NHL	B-cell malignancies	+ parsaclisib	**Trial expected to start in 2021**
Other r/r NHL	B-cell malignancies	+ lenalidomide + plamotamab[1]	**Trial expected to start in 2021**

PoC Pivotal

Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys. Monjuvi (tafasitamab-cxix) is a CD19-directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).

1. In collaboration with and sponsored by Xencor

ASH 2020: CONCLUSIONS AND TAKE-AWAYS



- **REACH3 is first ever** successful Phase 3 trial in patients with chronic GVHD
- sNDA for ruxolitinib in preparation in the U.S.; global GVHD submissions planned by Novartis

- **Ruxolitinib has transformed outcomes** for thousands of MPN patients
- ASH data show potential for further growth, including in previously unstudied populations

- **New Drug Application** seeking approval in r/r NHL planned for H2 2021
- Combination opportunities (MPNs w/ ruxolitinib and NHLs w/ tafasitamab) already being explored

- **ASH data further reinforce** attractive profile as backbone of combination therapy in NHL
- firstMIND safety data used to inform design of Phase 3 frontMIND trial in 1L DLBCL

1. Development of ruxolitinib in GVHD in collaboration with Novartis.
2. Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys.

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