Immunochemotherapy plus lenalidomide for high-risk mantle cell lymphoma with measurable residual disease evaluation

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Supplemental Table 1. High risk status vs *TP53* alteration.

***TP53* alteration**	**High Risk***		**Total**	***P* value[1]**
	N	Y		
				0.006
Wildtype	11 (73%)	16 (59%)	27 (64%)	
Deletion	4 (27%)	1 (3.7%)	5 (12%)	
Mutation	0 (0%)	1 (3.7%)	1 (2.4%)	
Mutation and deletion/loss of heterozygosity	0 (0%)	9 (33%)	9 (21%)	
Total	15 (100%)	27 (100%)	42 (100%)	

*All samples with bi-allelic inactivation of *TP53* are included in the high-risk group per protocol

[1]Fisher's exact test

N, no; Y, yes

Supplemental Table 2. Progression-Free Survival According to MRD Status

Assay sensitivity	Time point							
	Len-R-CHOP		R-HiDAC		EoT		6 months post-EoT	
	Positive/ total[1]	HR (95% CI)[2]	Positive/ total[1]	HR (95% CI)[2]	Positive/ total[1]	HR (95% CI)[2]	Positive/ total[1]	HR (95% CI)[2]
1 x 10^{-5}	12/37 (32%)	1.56 (0.63, 3.87)	0/35 (0%)	--	3/36 (8.3%)	33.9 (5.45, 210)	3/29 (10%)	1.48 (0.32, 6.78)
1 x 10^{-6}	21/33 (64%)	3.10 (1.12, 8.61)	5/25 (20%)	3.70 (1.22, 11.3)	5/28 (18%)	5.90 (1.85, 18.8)	12/29 (41%)	4.79 (1.74, 13.2)

[1]n/N (%)
[2]HR = Hazard Ratio

Supplemental Table 3. PET-MRD Concordance at 1E5 Sensitivity*

Study time point	MRD status	PET Result		PET-MRD Pairs	Concordance
		5PS 1-3	5PS 4-5		
Len-R-CHOP	Detectable	9	3	37	68%
	Undetectable	22	3		
R-HiDAC	Detectable	0	1	37	95%
	Undetectable	34	2		
R-lenalidomide	Detectable	2	2	37	95%
	Undetectable	33	0		
Overall				111	85%

*5PS "X" scans were adjudicated according to the clinical impression: complete response 5PS 1-3, partial response or progression, 5PS 4-5

MRD, measurable residual disease; 1E-5, 1 x 10^{-5}; 5PS, five-point scale

Supplemental Table 4. Grade ≥3 Non-hematologic toxicity (all grade 3).

AE	CTCAE category	Timepoint
Cardiac disorders – other specify – Takotsubo cardiomyopathy	Cardiac disorders	Len RCHOP C4
Constipation	Gastrointestinal disorders	Len RCHOP C2
Edema limbs	General disorders and administration site conditions	Len Rmain C2
Chest Pain	General disorders and administration site conditions	R-HiDAC C1
Fatigue	General disorders and administration site conditions	R-HiDAC C1
Lung infection	Infections and infestations	Len Rmain C4
Skin infection	Infections and infestations	Len Rmain C3
Sepsis	Infections and infestations	R-HiDAC C1
Lung infection	Infections and infestations	Len Rmain C1
Hyperglycemia	Metabolism and nutrition disorders	Len RCHOP C1
Joint effusion	Musculoskeletal and connective tissue disorders	Len Rmain C2
Right knee pain	Musculoskeletal and connective tissue disorders	R-HiDAC C1
Polyarthralgia	Musculoskeletal and connective tissue disorders	Len Rmain C2
Syncope	Nervous system disorders	Len RCHOP C3
Rash maculo-papular	Skin and subcutaneous tissue disorders	Len Rmain C4
Rash maculo-papular	Skin and subcutaneous tissue disorders	Len Rmain C2
Rash	Skin and subcutaneous tissue disorders	Len RCHOP C2
Hypertension	Vascular disorders	Len RCHOP C2
PGOT elevation		Len RCHOP

Supplemental Table 5: OS by CR Status following len-R-CHOP (N = 47 evaluable patients)

Characteristic	N		36-month OS from EOT (months)	Median OS from EOT (months)	P[2]
	Overall[1]	OS events[1]			
CR status at post-len-R-CHOP					0.065
<CR	8	4	47% (21%, 100%)	22 (8.8, —)	
CR	39	10	81% (70%, 95%)	— (—, —)	

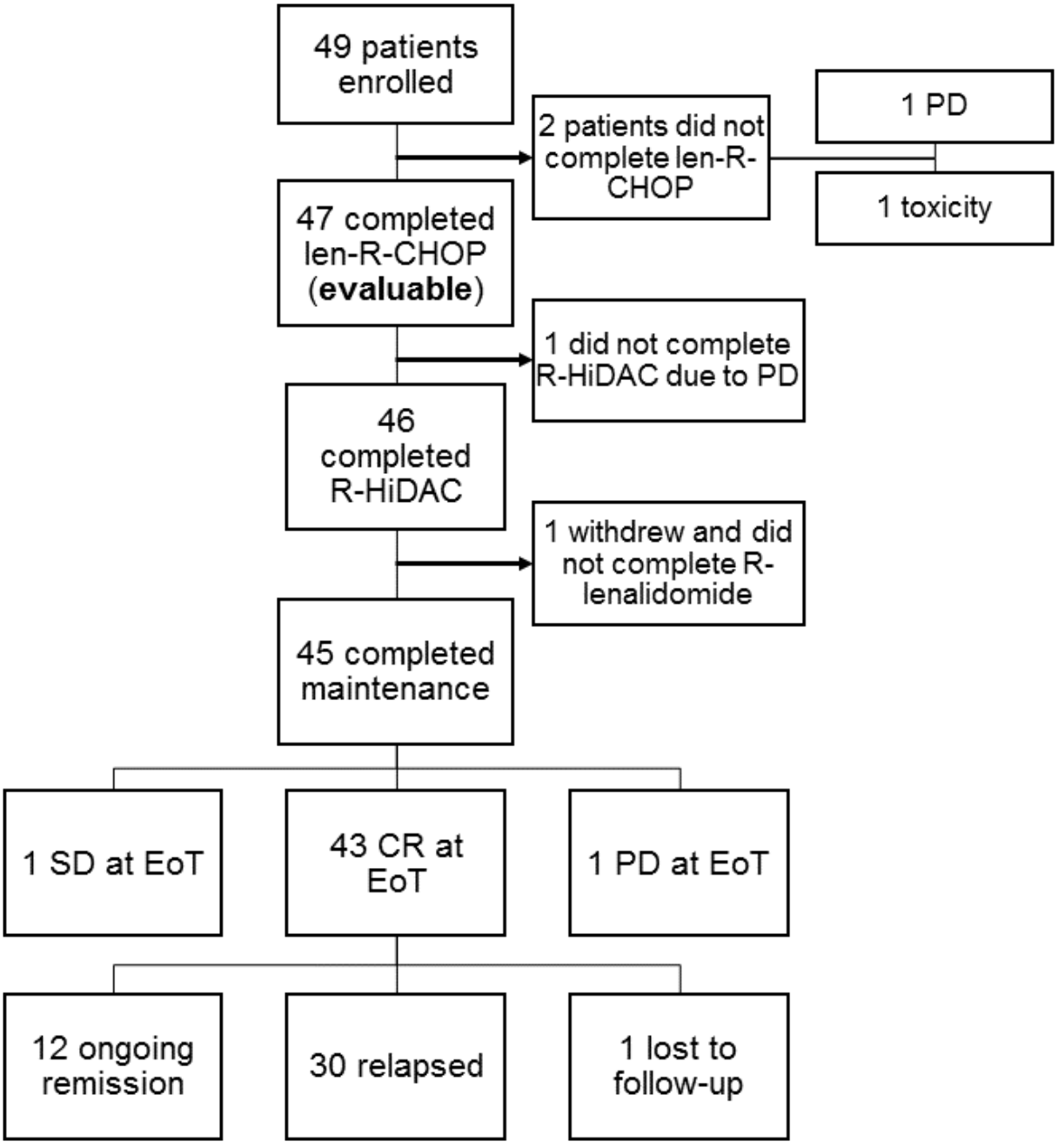
[1]n

[2]Log-rank test

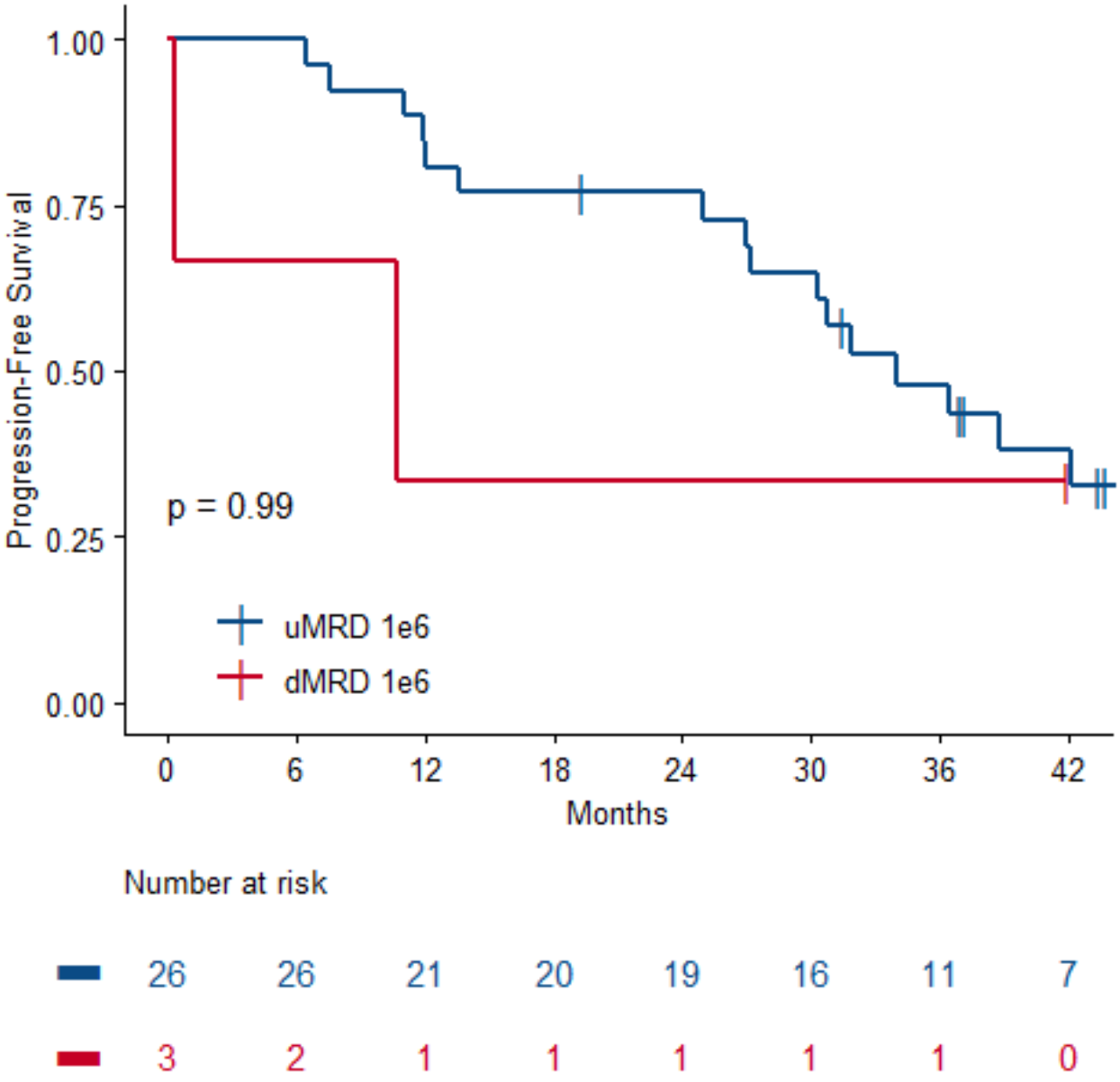
Supplemental Figure 1

CONSORT diagram. PD indicates progressive disease; CR, complete response; SD, stable disease; EoT, end-of-treatment

Figure 2. CONSORT diagram



Supplemental Figure 2. Progression-free survival by MRD status at 10e5 at 6 months post-EoT



Number at risk

uMRD 1e6	26	26	21	20	19	16	11	7
dMRD 1e6	3	2	1	1	1	1	1	0