



2012...2015

T-Cell Lymphomas: We are illuminating the darkest of tunnels
Bologna, Royal Hotel Carlton, April 27-29, 2015

BENDAMUSTINE IN PTCL

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STILL A LOT TO DO FOR PTCLs

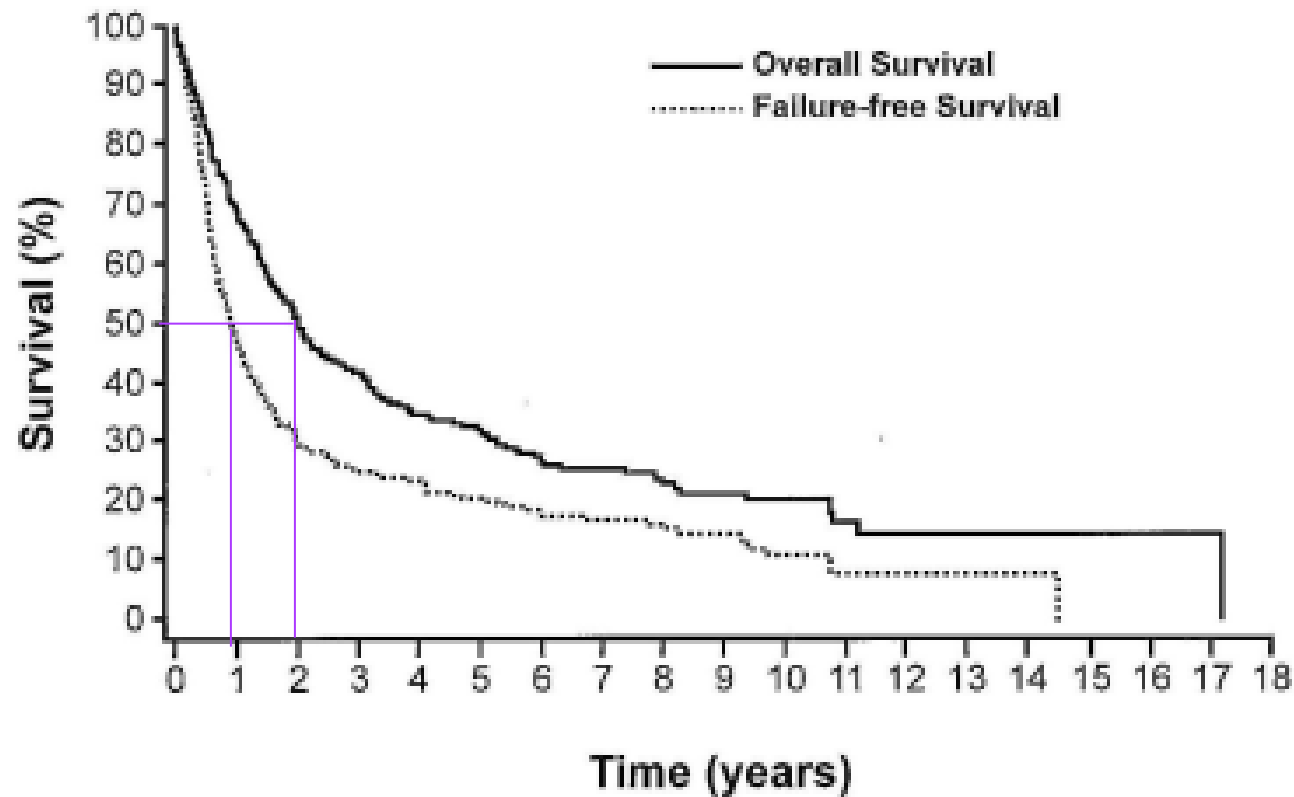
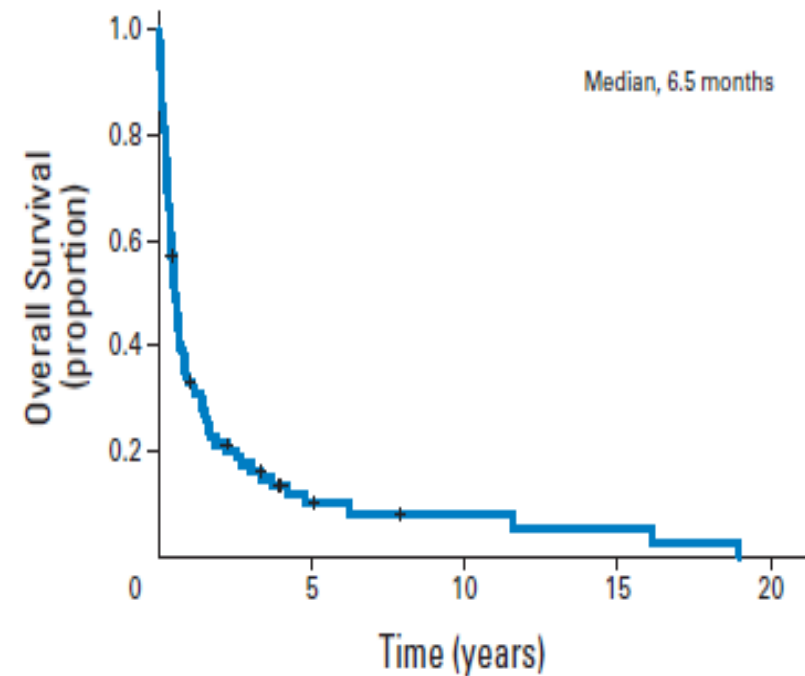
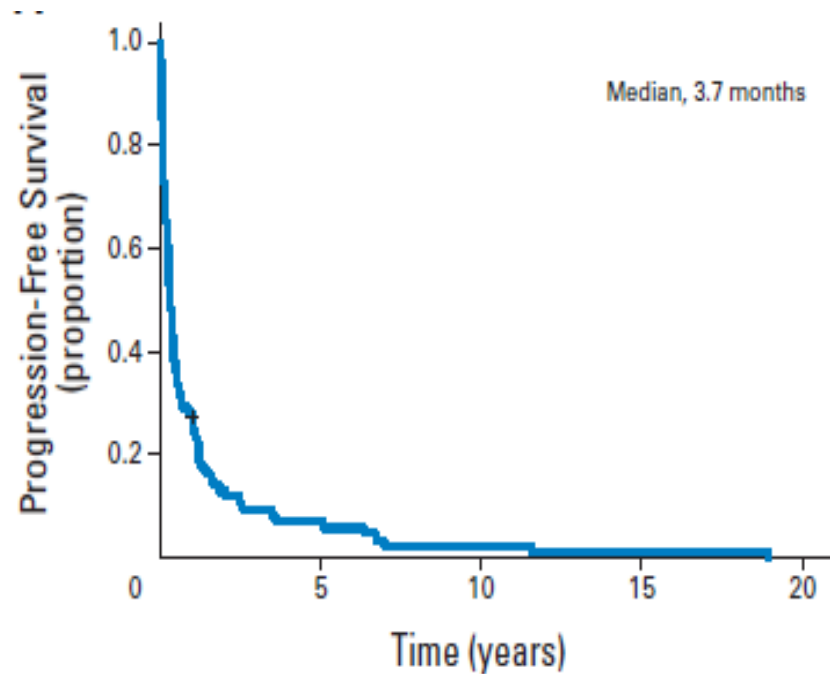


Figure 1. OS and FFS of 340 patients with PTCL-NOS.

PTCL : RELAPSE / REFRACTORY

- Median time from PTCL diagnosis to relapse or progression : 6 – 7 months
- Progression Free Survival¹ : 3.7 months
- Poor overall survival¹ : 6.5 months



DATA ON BENDAMUSTINE IN PTCL

Published

- **BENTLY study: prospective** (Damaj et al, JCO 2012)
- **Italian Study : retrospective** (Zaja et al, Annals of hematology 2013)
- **French study : retrospective** (Herbaux et al, British Journal of Haematology 2014)

Unpublished

- **Real-life use of Bendamustine in PTCL in France**

MAIN CHARACTERISTICS OF PUBLISHED STUDIES

	Damaj et al (2012) (n= 60)	Zaja et al (2013) (n= 20)	Herbaux et al (2014) (n= 15)
Study	Prospective	Retrospective	Retrospective
Histology	AITL PTCL-nos	PTCL-nos, AITL, MF/Sezary T-PLL, LGL	T-PLL
Dose; mg/m ² ; (range)	120	90 (60 –100*)	100 (70-120**)
Schedule duration	D1-2/21 d	D1-2	D1-2/21 d
N° cycles	4 (1-6)	2 (1-8)	4 (1-6)
N prior line; (range)	1 (1-3)	2 (0-8) (1 st line=1)	1 (0-3) (1 st line= 6 pts)
Refractory; %	45	68	-
Response; %			
CR+CRu+PR	50	55	53
CR+CRu	28	10	20
m DoR; mo	3.5 (1 – 20.7)	-	12.5 (2-13)
m PFS; mo (range)	3.6 (2.4-5.2)	6mo 44% -	5 -
m OS, mo (range)	6.3 (5.2-9.6)	6mo 67% -	8.7 (1-27)

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REAL LIFE USE OF BENDAMUSTINE IN PTCL IN FRANCE

**Patients selection: National registry data on the use of chemotherapy
Q3-2011 – Q4-2014**



**200 patients
T-cell neoplasms
were treated with bendamustine**



**96 patients
« Collection of more data is ongoing »**

PATIENTS' CHARACTERISTICS AT BENDAMUSTINE

Patients (n)	96
Age , median (range; (years)	65 (28-89)
> 75 years n(%)	21 (22)
Male/female (n)	55/41
Histology, n (%)	
AITL	43 (45)
PTCL-nos	31 (32)
sALCL	9 (10)
MF	4 (5)
Others	8 (8)
Disease stage; n (%)	
Stage II	4 (4)
Stage III/IV	87 (91)
IIB / IVA	4 (5)
IPI; n (%)	
1 – 2	4 (4)
3 – 5	87 (91)
Bone marrow involvement; n (%)	
yes	29 (30)
no	35 (36.5)
Blood involvement; n (%)	
yes	11 (11)
no	84 (87)
Extra-nodal sites involvement n(%)	67 (70)

PATIENTS' CHARACTERISTICS AT BENDAMUSTINE

Patients (n)	96
Previous line of treatment; median (range)	2 (1-5)
0; n(%)	4 (4)
1 line, n(%)	32 (33)
2 lines, n(%)	39 (41)
≥ 3 lines, n(%)	21 (22)
Better response before bendamustine; n(%)	
CR + PR	45 (49)
Stable	3 (4)
Progressive	43 (47)
Prior therapy; n (%)	
ASCT transplantation	9 (10)
CHOP/CHOP like regimen	84 (91)
Time from diagnosis to bendamustine median (range; mo)	13.4 (0.4 - 108)
Duration of the best previous response median (range; mo)	4.6 (1 – 70)

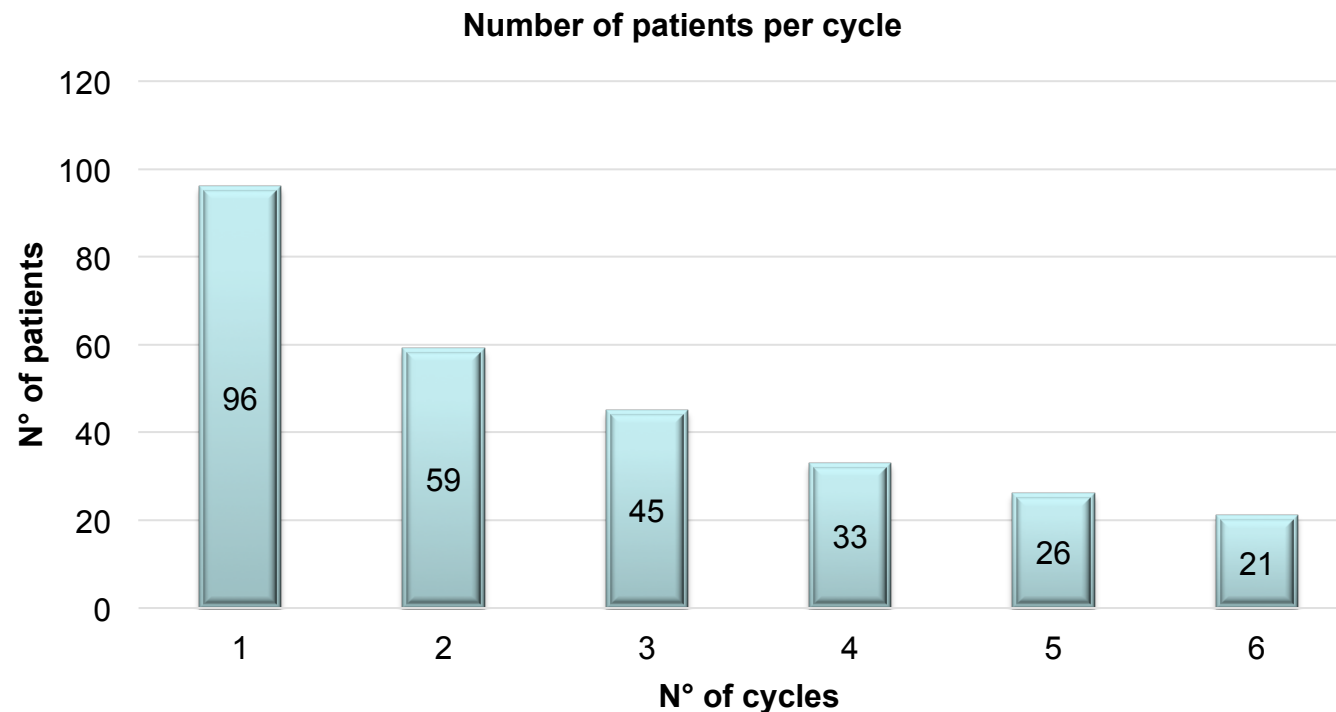
BENDAMUSTINE ADMINISTRATION

Patients (n)	96
Dose; median (mg/m ²) (range)	90 (40 - 150)*
N° of cycles; median (range)	2 (1 – 6)
Patients; n (%)	
< 90 mg/m ²	15 (16)
≥ 90 mg/m ²	81 (84)

*bendamustine

> 120 mg/m² = 1 patient

< 70 mg/m² = 6 patients



RESPONSE TO BENDAMUSTINE

<i>Response</i>	<i>as by Local Investigator</i>	
<i>(Total N° = 91)</i>	<i>N°</i>	<i>%</i>
Best Overall Response Rate		
CR+PR	33	36
Complete response	25	27
<i>(PET negative)</i>	13	
Partial response	13	9
Stable	2	2
Progressive	56	61
Time to response; median (range, mo)	2.8 (0.4-11)	
Duration of response; median (range, mo)	5.1 (1 – 49)	

RESPONSE BY HISTOLOGIC SUBTYPES

	N	CR (%)	PR (%)	PD (%)	ORR (%)
All Patients	91	27	9	61	36
AITL	43	18 (42)	5 (11)	20 (46)	23 (53)
PTCL-nos	30	4 (13)	2 (6.5)	23 (76)	6 (20)

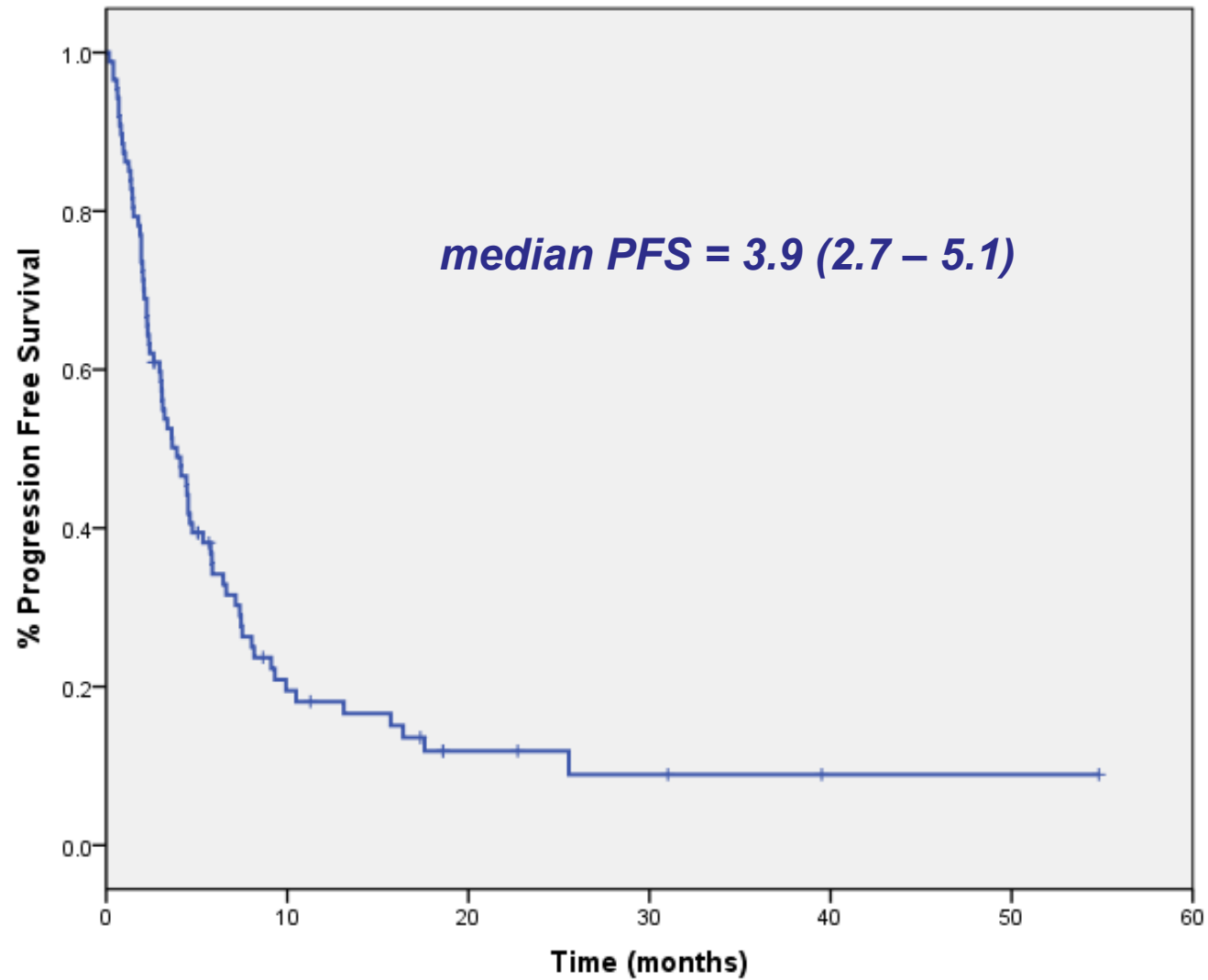
RESPONSE ACCORDING TO BENDAMUSTINE DOSAGE

	N	CR (%)	PR (%)	PD (%)	ORR (%)
< 90 mg/m ²	14	4 (28)	0	10 (72)	4 (28)
≥ 90 mg/m ²	76	20 (26)	12 (16)	46 (60)	32 (42)

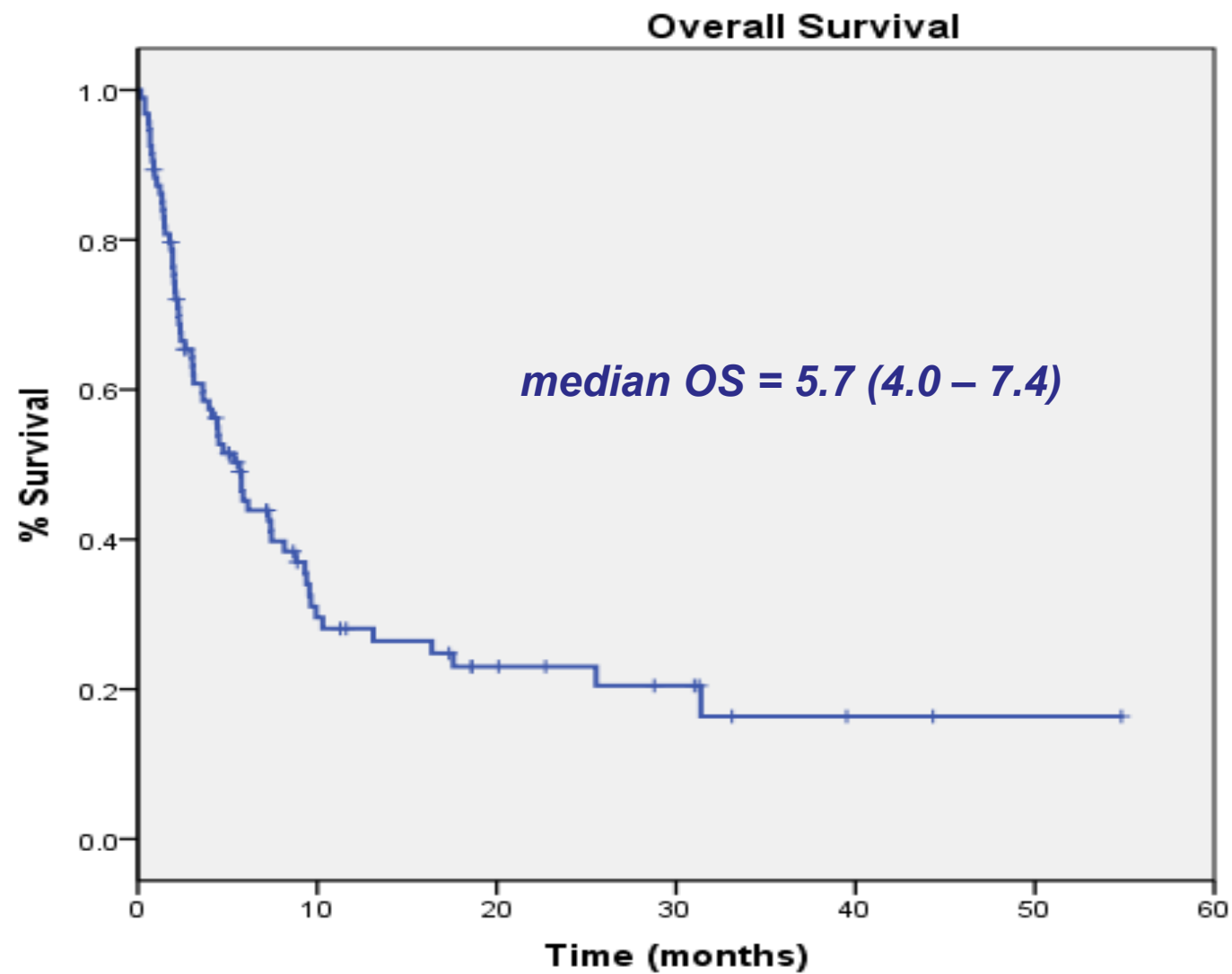
RESPONSE ACCORDING TO KEY SUBSETS

Characteristics	N	ORR	
		%	<i>p</i>
Age (years)			
<65	44	29	0.13
≥65	46	46	
Histology			
AITL	43	53	0.01
PTCLu	30	23	
Status prior to benda			
Sensitive	45	53	0.03
Refractory	38	21	
N° of prior lines			
1 line	33	51	0.04
≥ 2 lines	57	30	
Bone marrow involvement			
yes	26	31	0.9
no	33	48	

Progression Free Survival



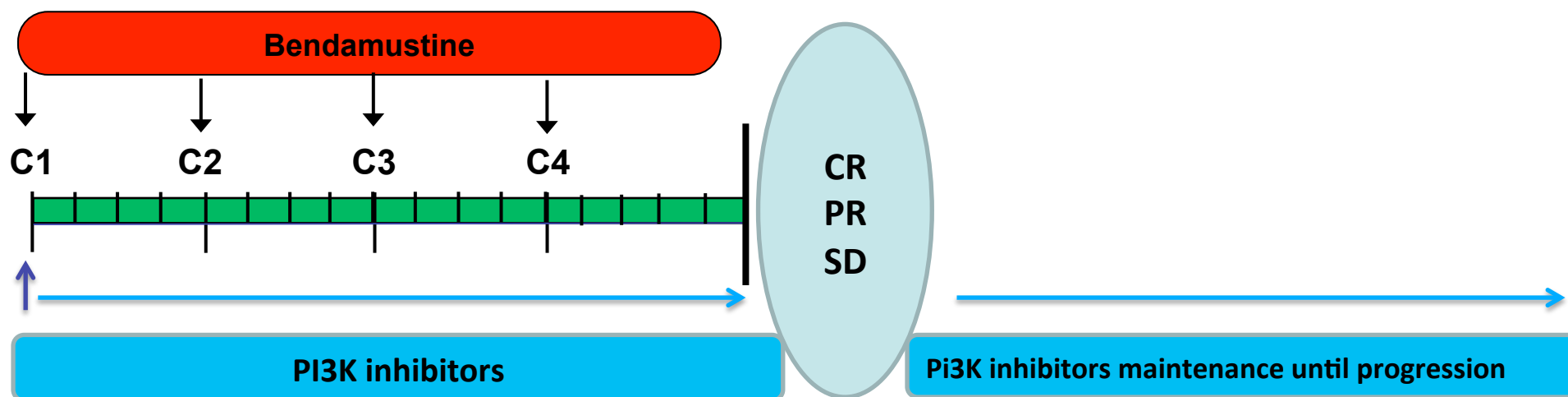
Overall Survival



TOXICITIES

	Grade 3/4 n (%)
Thrombocytopenia	19 (20)
Neutropenia	13 (14)
Infections	
G ½	54 (56)
G ¾	14 (15)

CONCLUSION / PERSPECTIVES



Primary Objective

ORR (CR + CRu + PR)

Secondary objectives

To evaluate the safety of the combination

Duration DOR

PFS, OS

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