Gemeinschaftsklinikum Mittelrhein

ASCO 2023 Highlights - Sarkome

2023 ASCO ANNUAL MEETING

A Multicenter Phase II Study of Cabozantinib + Nivolumab for Patients with Advanced Angiosarcoma Previously Treated with a Taxane

Alliance A091902

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Abstract #11503

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

NCI National Clinical Trials Network

Background

- Angiosarcoma (AS) is a rare, aggressive vascular malignancy
  - High rate of local/distant recurrence
    - 5 yr OS of 30-40%
  - Weekly paclitaxel is one SOC option for AS[1-2]
    - ORR 16 – 45%
    - Median PFS 3.8 – 6.6 mo
    - Median OS 8.3 – 19.5 mo
  - Doxorubicin (pooled analysis)[5]: PFS 4.9 mo, OS 9.9 mo
- Overexpression of VEGF
  - Limited activity of VEGFR inhibitors[4-5]
    - ORR 8 – 10%
    - Median PFS 2 – 4 mo
    - Median OS 9.7 – 13 mo
  - TAPPAS trial: TRC105 +/- pazopanib[6]: no difference (PFS 4.2 *vs.* 4.3 mo)

[1]Penel J Clin Oncol 2008; [2]Ray-Coquard J Clin Oncol 2015; [3]Young, EJC 2014; [4]Ray-Coquard Oncologist 2012; [5]Agulnik Ann Oncol 2013; [6]Jones JAMA Onc 2022

Angiosarcoma: Immune checkpoint inhibition

- Subset of angiosarcoma are TMB high, variable PD-L1 expression[1]
  - Predominantly UV exposed areas of scalp/face
- Case reports, small case series of responses to ICI
- Alliance A091401[2]: PR in 1 of 3 AS patients on ipi/nivo arm
- DART (dual IO trial)[3] – AS cohort: ORR 25% (4/16)
  - Responses seen in patients with cutaneous disease (3/5) and radiation associated breast AS (1/3)

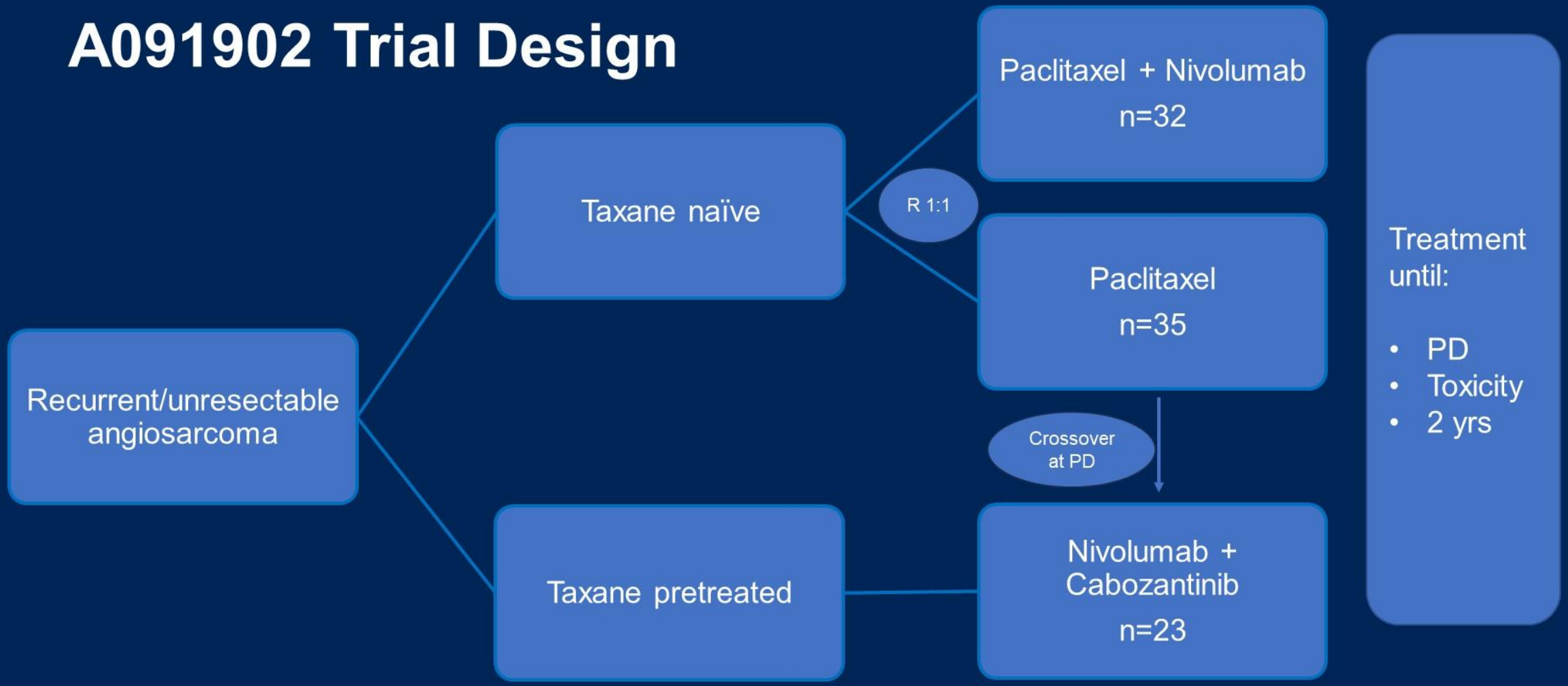
[1]Painter C. et al. *Nat Med* 2020; [2]D'Angelo Lancet 2018; [3]Wagner JITC 2021

Phase II trial: Cabozantinib + Nivolumab for patients with advanced angiosarcoma previously treated with a taxane (A091902)

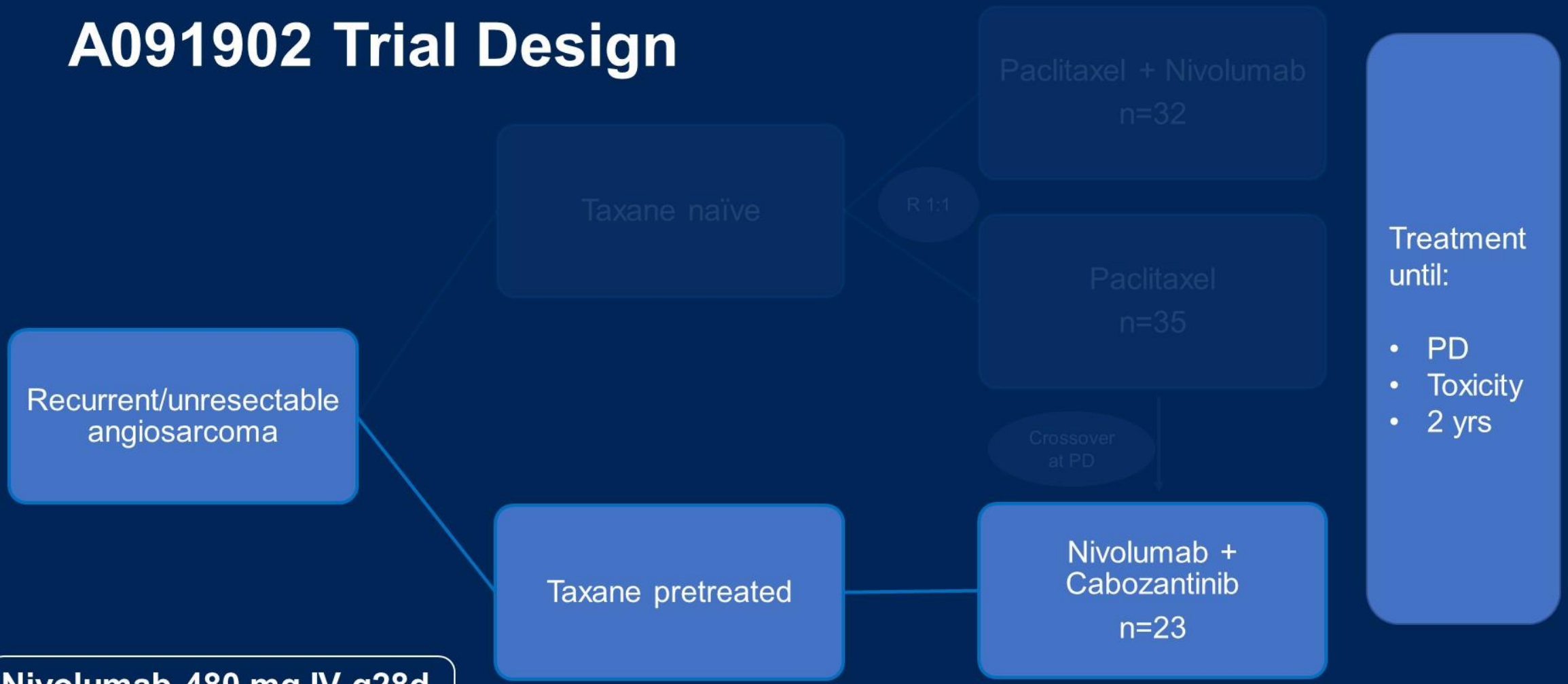
- Combined VEGFR and PD-1/PD-L1 axis blockade have shown potentially synergistic benefit in a variety of cancers

- Hypothesis: Cabozantinib plus nivolumab will be effective in angiosarcoma, across subtypes

A091902 Trial Design



A091902 Trial Design



Nivolumab 480 mg IV q28d
Cabozantinib 40mg daily

Tx beyond PD in 1st 12 wks permitted; 4 wk confirmatory scan required

Cabozantinib/Nivolumab in Angiosarcoma

Patient Characteristics n=22	
Age, yrs	67 (32 – 92)
Race (Asian/Black/White)	1/2/19
Female	11 (50%)
ECOG PS 0	8 (36%)
Primary disease site	
Cutaneous (scalp/face)	13 (59%)
Liver	1 (5%)
Breast	4 (18%)
Other	2 (9%)
Prior cancer diagnosis	6 (27%)
Prior taxane for AS	22 (100%)
Adjuvant taxane for AS	11 (50%)
Prior anthracycline for AS	5 (23%)

Data cut off 5/3/2023

Cabozantinib/Nivolumab in Angiosarcoma

Summary of Response n=22	
Best Objective Status (n, %)	
CR	2 (9%)
PR	11 (50%)
SD	3 (14%)
PD	6 (27%)
Death/No Assessment	0
ORR (CR + PR)	13 (59%; 95% CI 47 – 90%)
Cutaneous scalp/face (n=13)	7 of 13 (54%; 95% CI 25 – 81%)
Non-cutaneous (n=9)	6 of 9 (67%; 95% CI 30 – 93%)

Cabozantinib/Nivolumab in Angiosarcoma

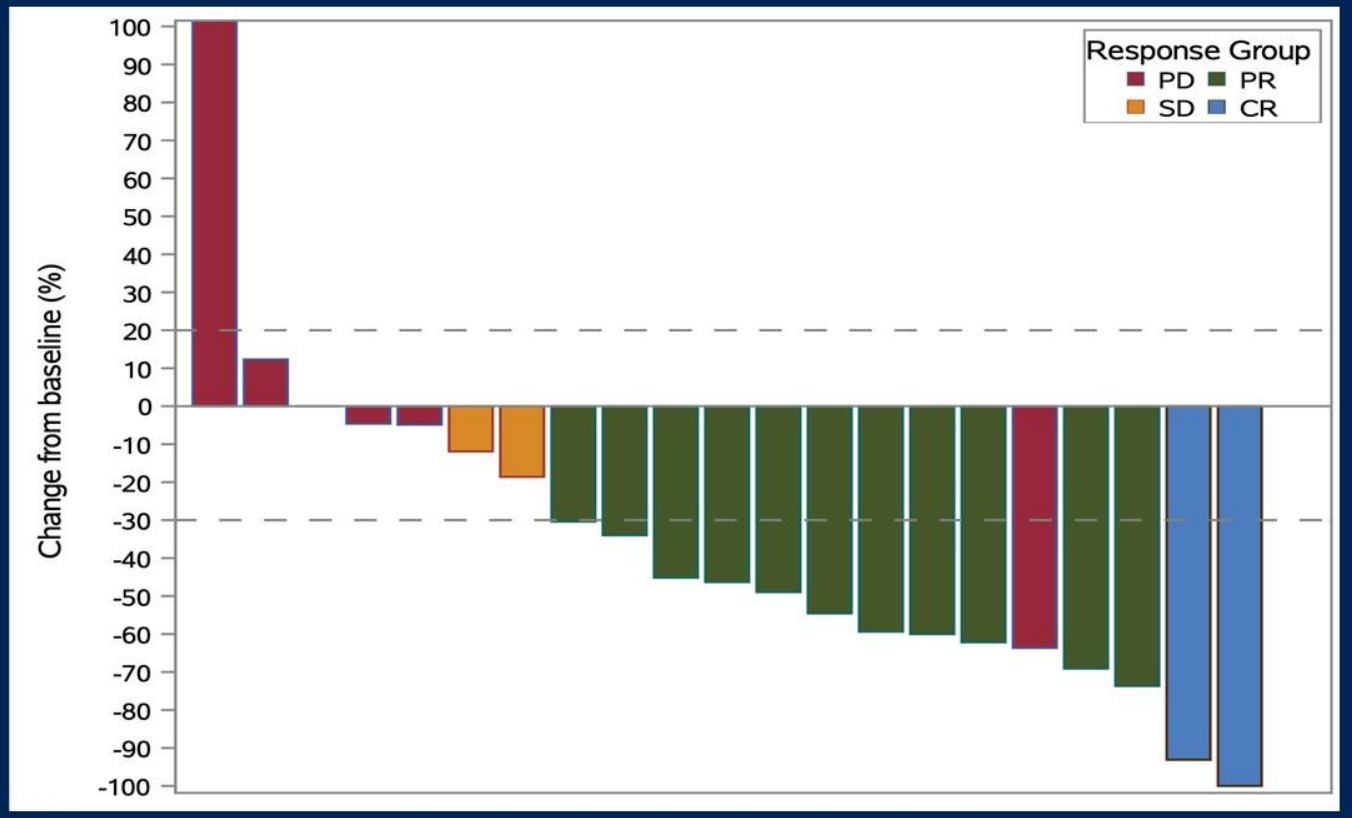
Best Overall Response: RECIST v1.1

Significant responses including 2 CRs

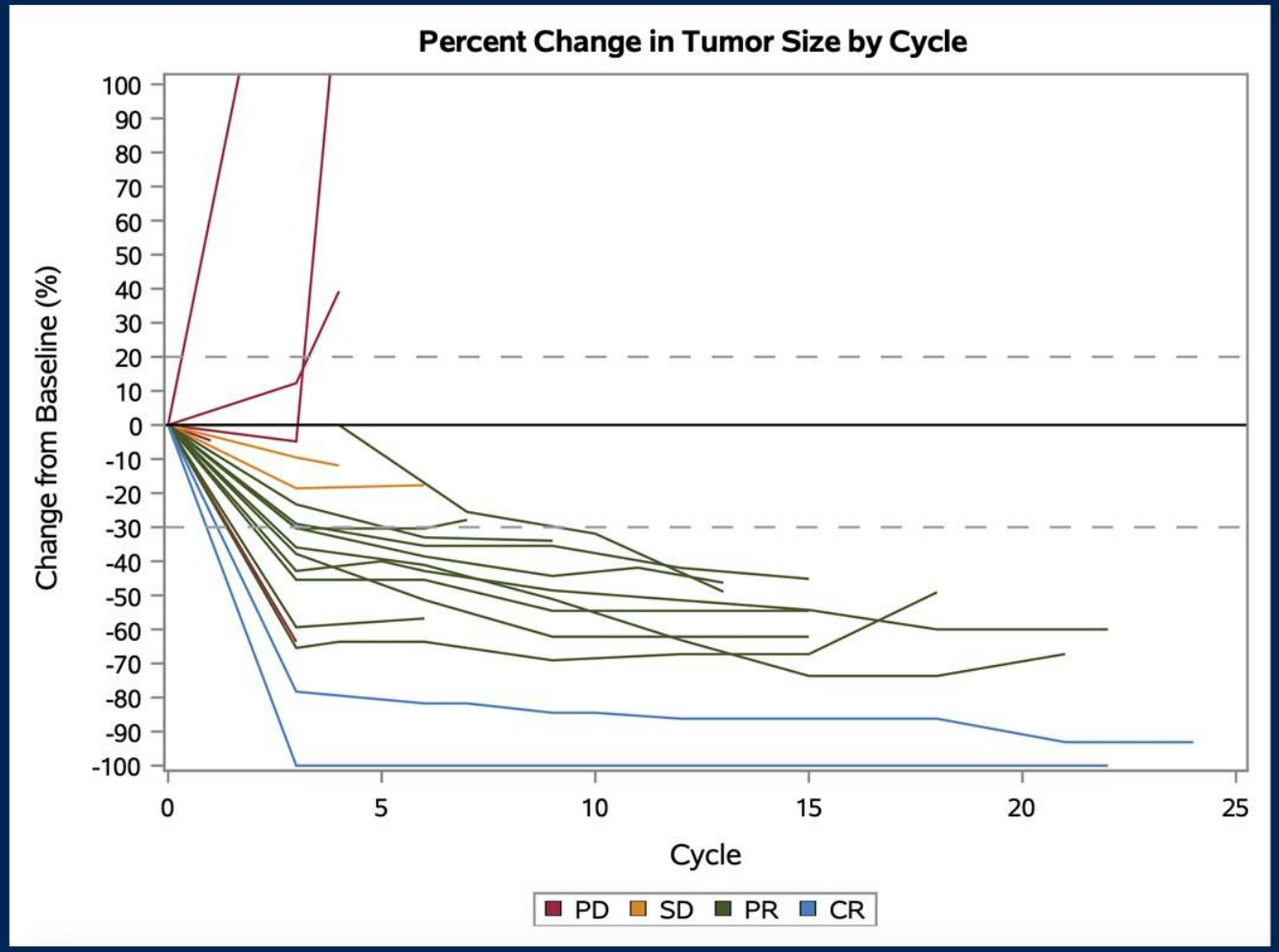
ORR 13/22 = 59%
(95% CI, 36 – 79%)

1st stage 8/9 (89%)

Overall CBR 16/22 (73%)



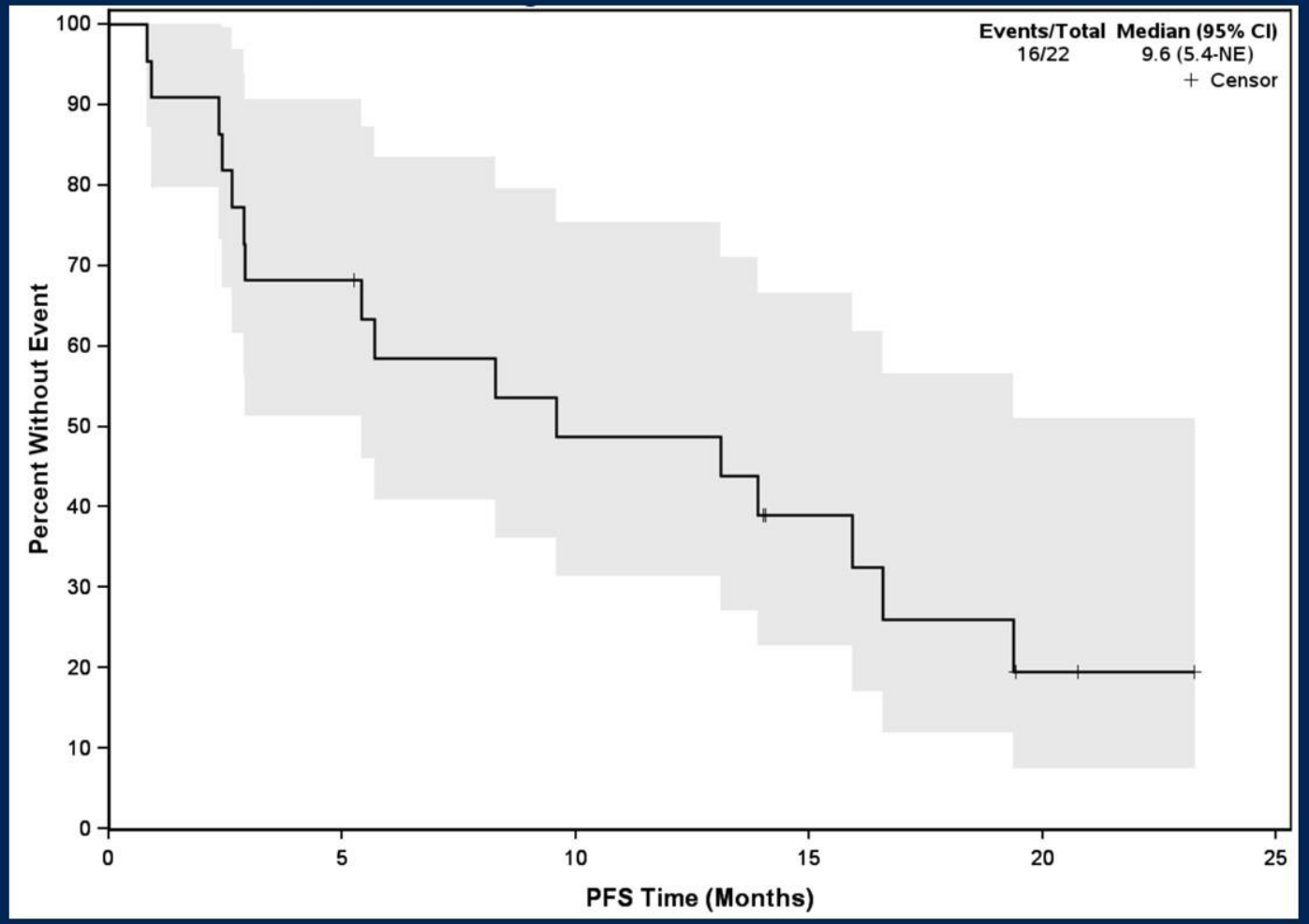
Cabozantinib/Nivolumab in Angiosarcoma
Rapid durable response



6 patients remain on study

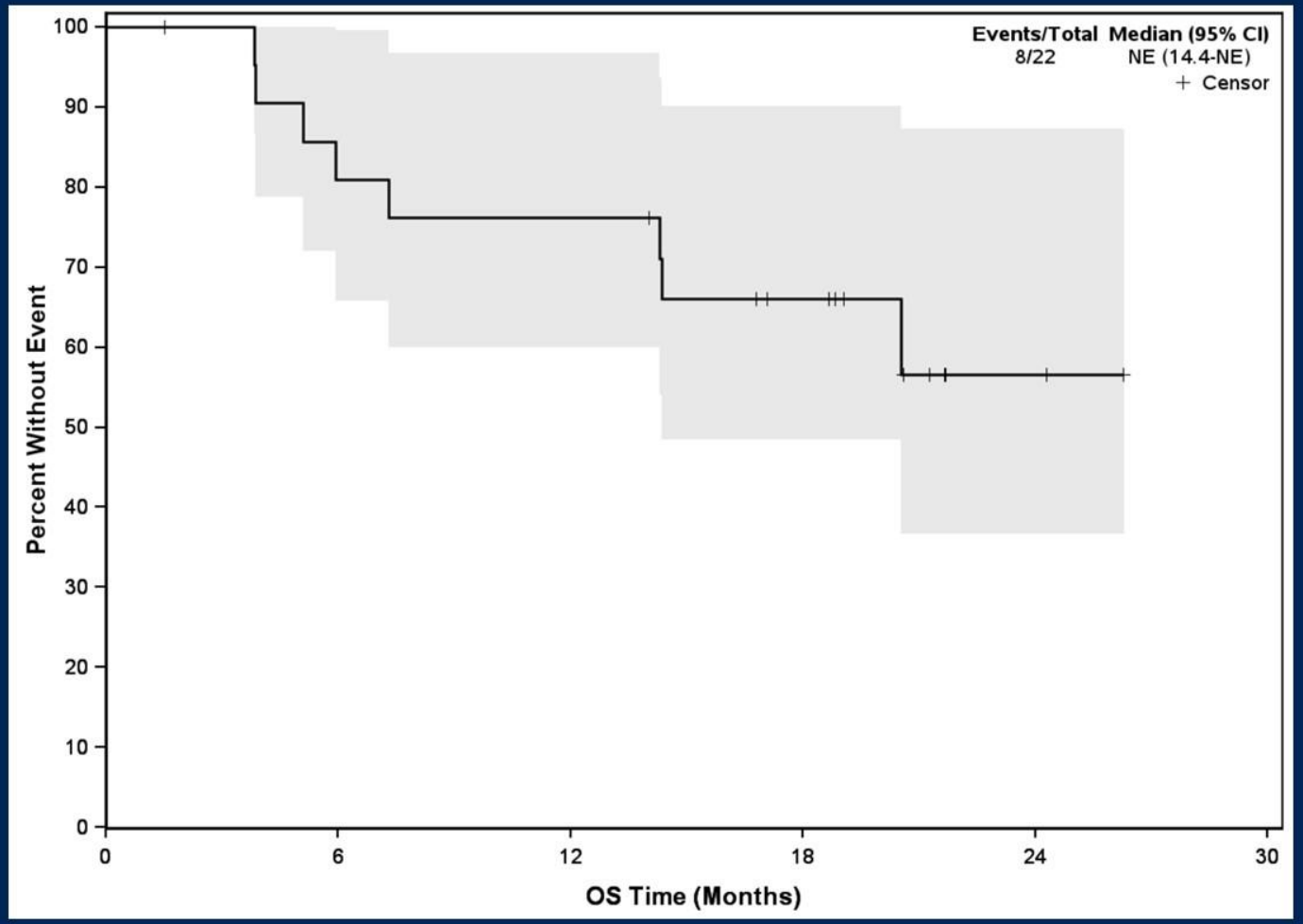
Cabozantinib/Nivolumab in Angiosarcoma

Median PFS: 9.6 mo (95% CI, 5.4 – NR)



Cabozantinib/Nivolumab in Angiosarcoma

Median OS: NR (95% CI, 14.4 – NR)



Cabozantinib + Nivolumab Safety Overview

Well tolerated with no unexpected AEs

	Grade 3	Grade 4
Adverse Events (AEs)	14	2
Hematologic	1	0
Non-hematologic*	13	2
At least possibly Treatment Related AEs	6	2

*G3:
Heme: Neutrophil count decrease
Non-heme: HTN n=7. Others: n=2 for glucose intolerance/hyperglycemia, n=1 each for MI, pericardial eff, hypothyroidism, diarrhea, tooth infection, fall, wt loss, hypokalemia, hypophosphatemia, muscle weakness, tumor pain, ataxia, headache, ICH, dyspnea, pleural effusion, palmar-plantar erythrodysesthesia, thromboembolic event.

*G4:
Heme: none
Non-heme: n=1 each of dyspnea and HTN

Reason for discontinuation	
Disease progression	15
Comorbid condition unrelated to angiosarcoma	1
Withdrawal	0
Death due to study	0
Remain on study	6

Conclusions

- Cabozantinib + nivolumab has significant antitumor activity in taxane pretreated angiosarcoma
- Cabozantinib + Nivolumab exceeded its primary endpoint (planned 10 → 35% ORR improvement)
  - ORR 59%
  - CBR 73%
- Median PFS (9.6 mo) double that of historic controls (4.2 mo[1])
- Responses were similar in cutaneous and noncutaneous
- The combination was well tolerated without new safety signals
- Correlative analyses and PRO-CTCAE/FACT-G are ongoing
- Rare tumor trial accrued quickly (June – Oct 2021) through NCTN
  - A091902 taxane naïve cohorts have recently completed accrual

[1]Jones JAMA Onc 2022

2023 ASCO ANNUAL MEETING

Efficacy and safety of nivolumab and trabectedin in pretreated patients with advanced soft tissue sarcomas (STS) - results of a phase II trial of the German Interdisciplinary Sarcoma Group (GISG-15, NitraSarc)

Peter Reichardt[1], Dimosthenis Andreou[2], Anne Flörcken[3], Thorben Groß[4], Stephan Richter[5], Torsten Kessler[6], Martin Kortüm[7], Christian A Schmidt[8], Bernd Kasper[9], Eva Wardelmann[6], Benedict Atzler[10], Disorn Sookthai[10], Daniel W Mueller[10], Daniel Pink[8, 11]

[1] Helios Klinikum Berlin-Buch, Medical School Berlin, Berlin, Germany. [2] Medizinische Universität Graz, Austria. [3] Charité–Universitätsmedizin Berlin, Berlin, Germany. [4] Universitätsklinikum Tübingen, Tübingen, Germany. [5] Universitätsklinikum Carl „Gustav Carus“, Dresden, Germany. [6] Universitätsklinikum Münster, Münster, Germany. [7] Universitätsklinikum Würzburg, Germany. [8] Universitätsmedizin Greifswald, Greifswald, Germany. [9] Universität Heidelberg, Mannheim Cancer Center (MCC), Mannheim, Germany. [10] Institut für Klinische Krebsforschung IKF GmbH am Krankenhaus Nordwest, Frankfurt Am Main, Germany. [11] Helios Klinikum Bad Saarow, Bad Saarow, Germany

NiTraSarc – study population

- locally advanced/unresectable or metastatic soft tissue sarcoma (no GIST)
- age ≥ 18 years
- ≥ 1 prior systemic therapy for sarcoma, including adjuvant systemic therapy (anthracycline-containing regimen)

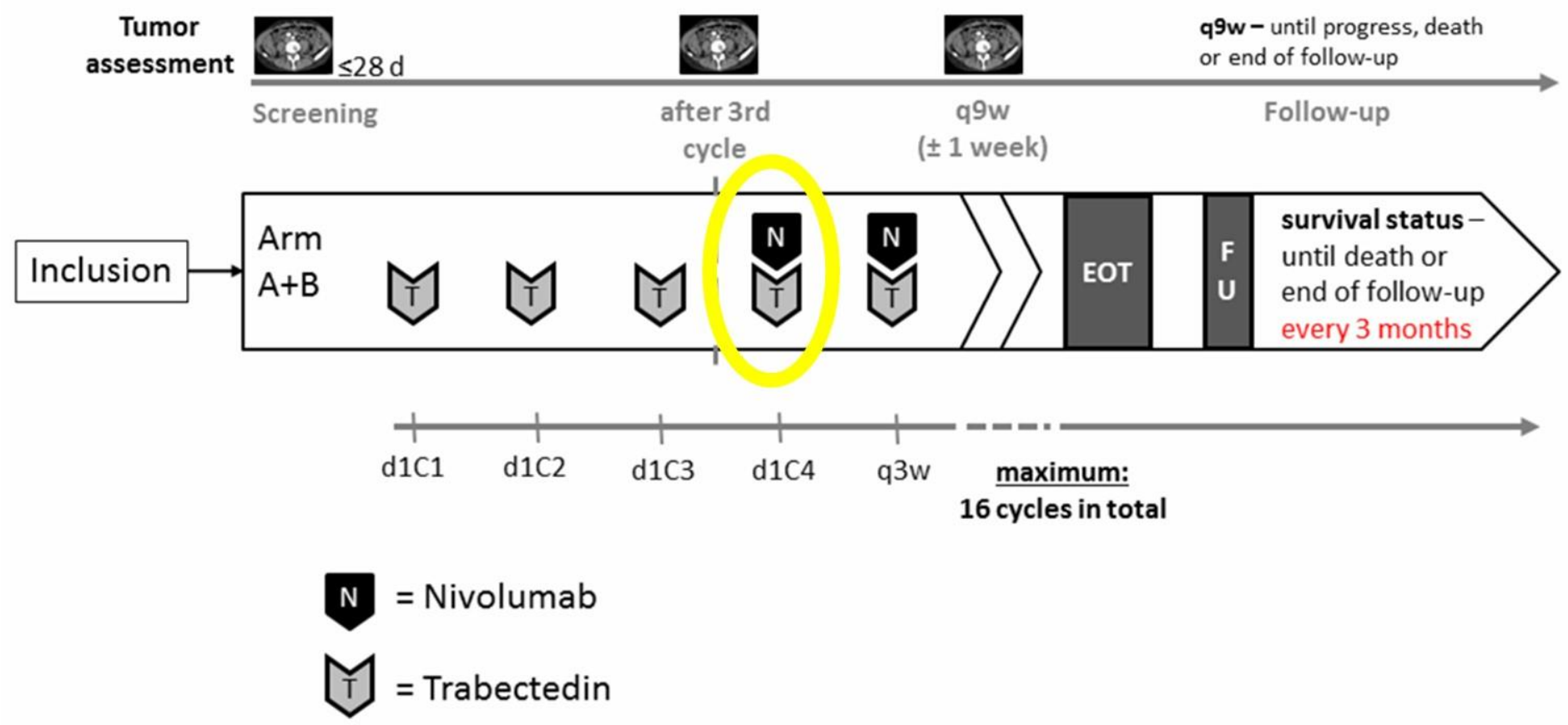
Group A (L-sarcoma):

- patients must have histologically confirmed liposarcoma or leiomyosarcoma

Group B (Non-L-sarcoma):

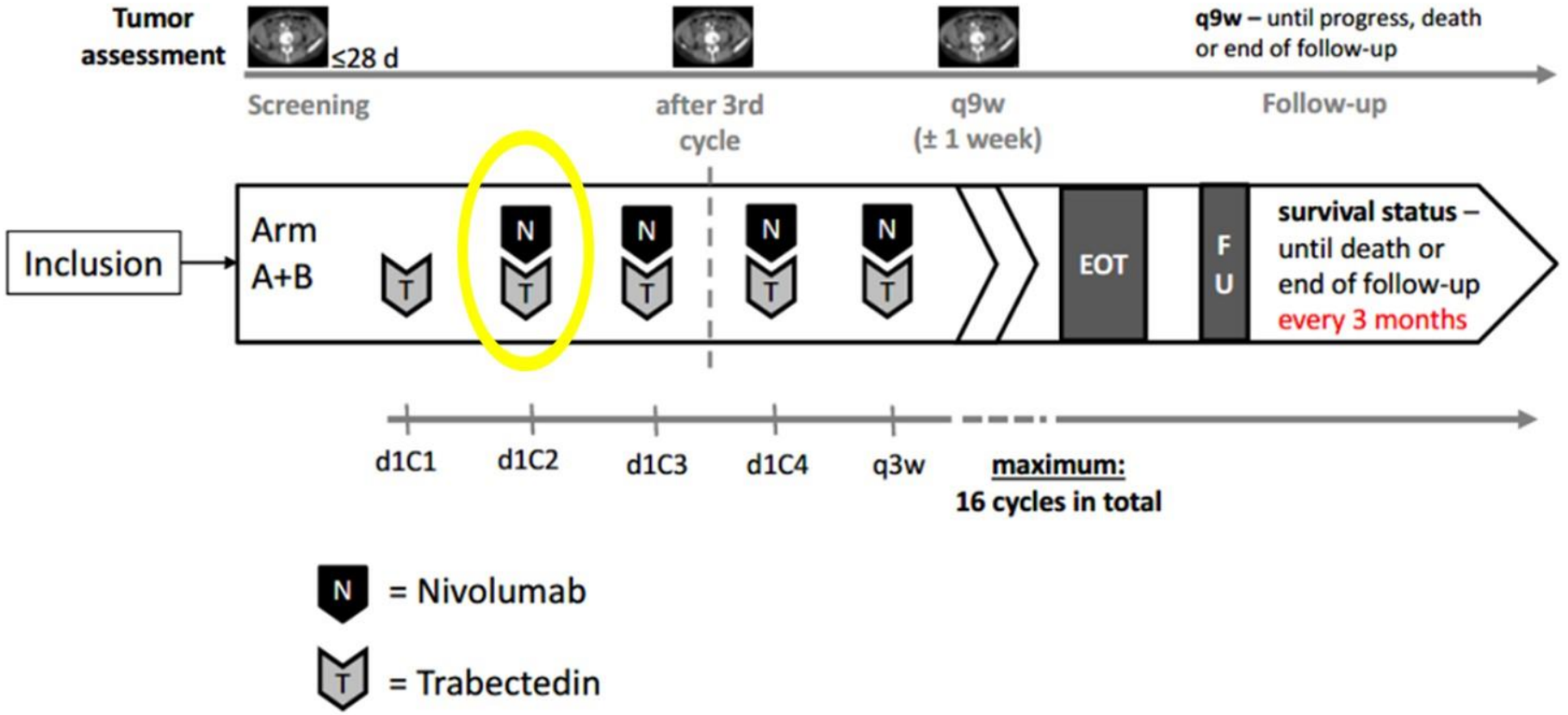
- patients must have histologically confirmed soft tissue sarcoma (STS) other than liposarcoma or leiomyosarcoma (GIST excluded)

Study Design (late combination cohort; LCC)



Study Design (early combination cohort; ECC)

Amendment after preplanned interim safety analysis and with new published data*



*Chawla SP, Sankhala KK, Ravicz JR, Kang GE, Liu S, Assudani N, et al. Clinical Experience with Combination Chemo-/Immunotherapy using Trabectedin and Nivolumab for Advanced Soft Tissue Sarcoma. J Sarcoma Res. 2018; 2(1): 1009.

Endpoints

Primary efficacy endpoint

- progression-free survival rate after 6 months (PFSR6) assessed by RECIST 1.1

Primary safety endpoint

- feasibility of combined treatment with trabectedin and nivolumab in patients with advanced or metastatic soft tissue sarcomas as determined by the safety and tolerability of the combination treatment

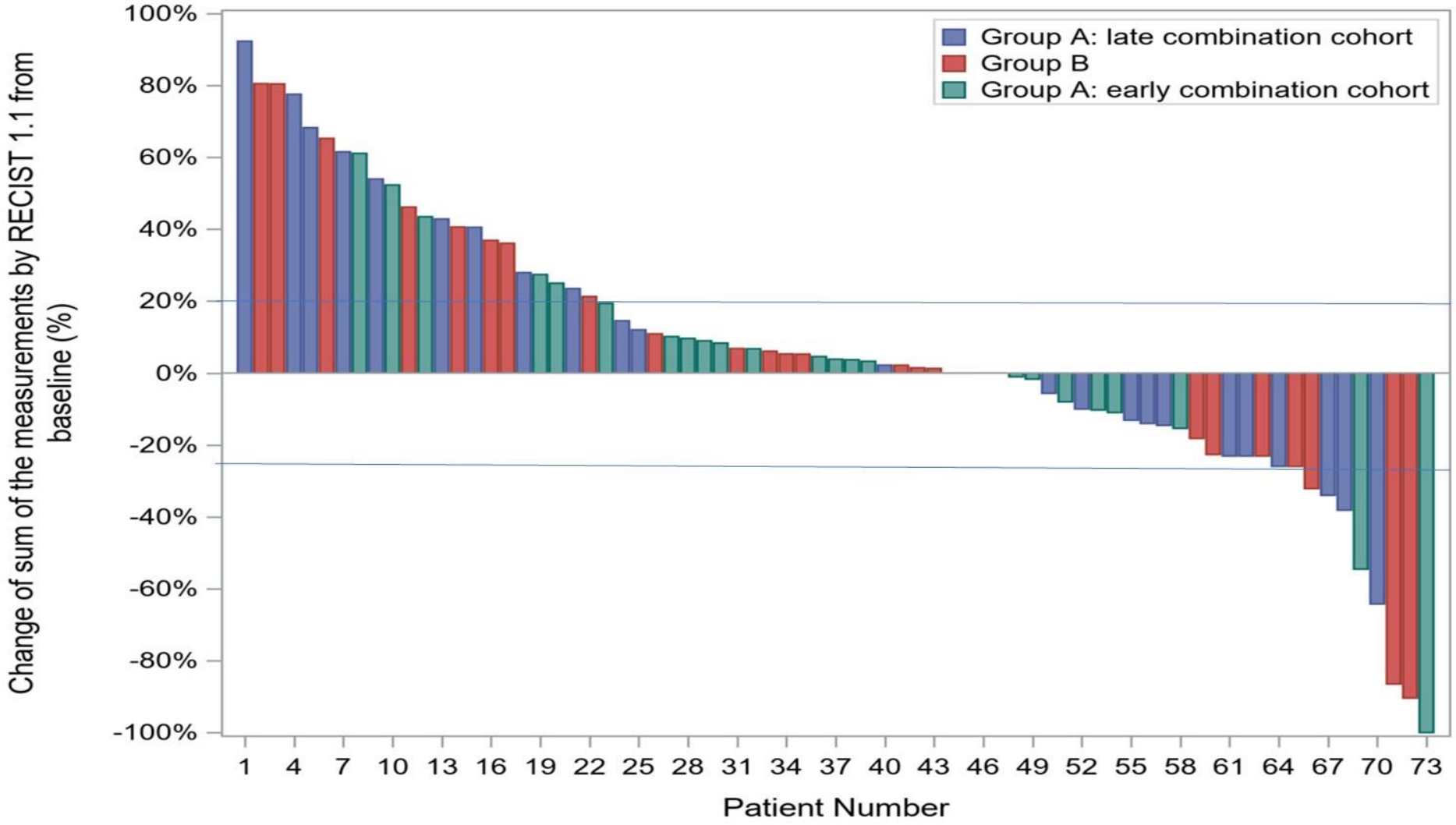
Interim safety analysis after treatment of 18 patients

Demographic data

	L-Sarcoma Group A		
	Early (n=23)	**Late** (n=20)	**Overall** (n=43)
Median **age** (range)	61 (43-75)	59 (40-80)	61 (40-80)
Female vs male	9:14	11:9	20:23
ECOG 0 vs 1	13:10	12:8	25:18
Leiomyosarcoma	11 (48%)	17 (85%)	28 (63%)
Liposarcoma	12 (52%)	3 (15%)	15 (37%)
Myxoid/round cell	4 (17%)	3 (15%)	7 (17%)
Dedifferentiated	8 (35%)		8 (20%)

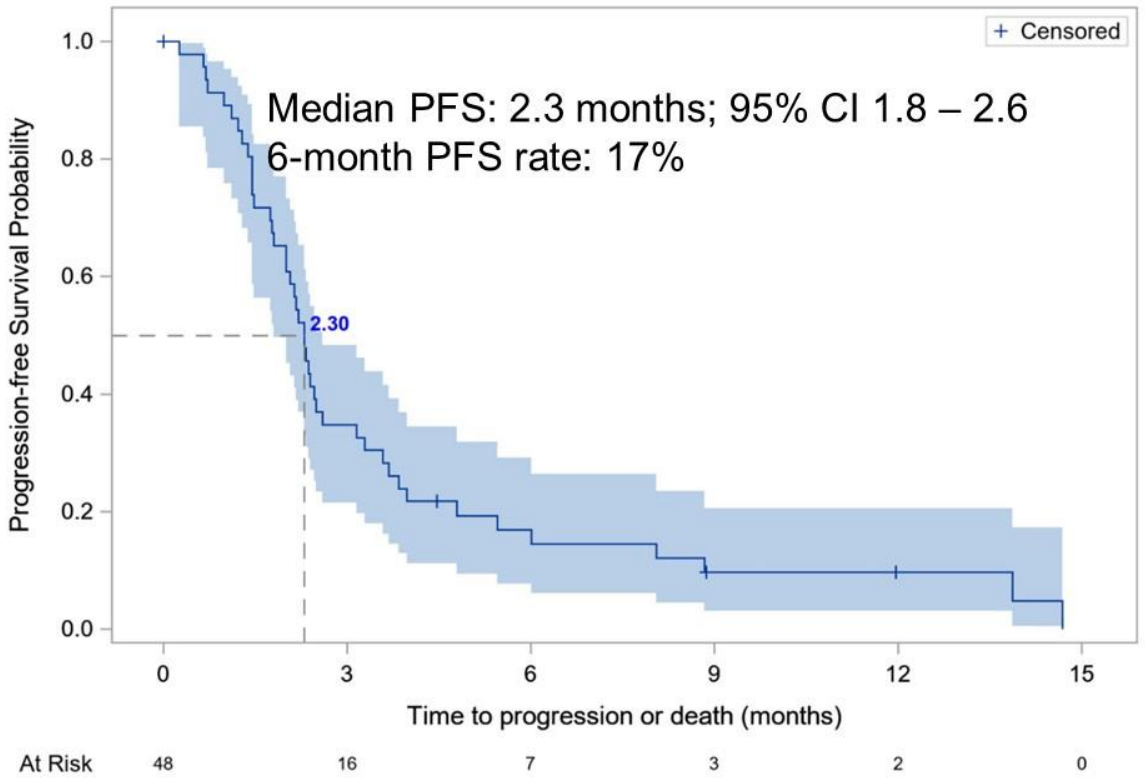
	Non-L-Sarcoma Group B
	Overall (n=49)
Median **age** (range)	53 (28-73)
Female vs male	18:31
ECOG 0 vs 1	26:23
Pleomorphic sarcoma	13 (27%)
Spindle cell sarcoma	11 (22%)
Fibromyxoid sarcoma	6 (12%)
Synovial sarcoma	5 (10%)
Other	14 (29%)

Responses: L-Sarcoma (Gr. A) + Non-L-Sarcoma (Gr. B)

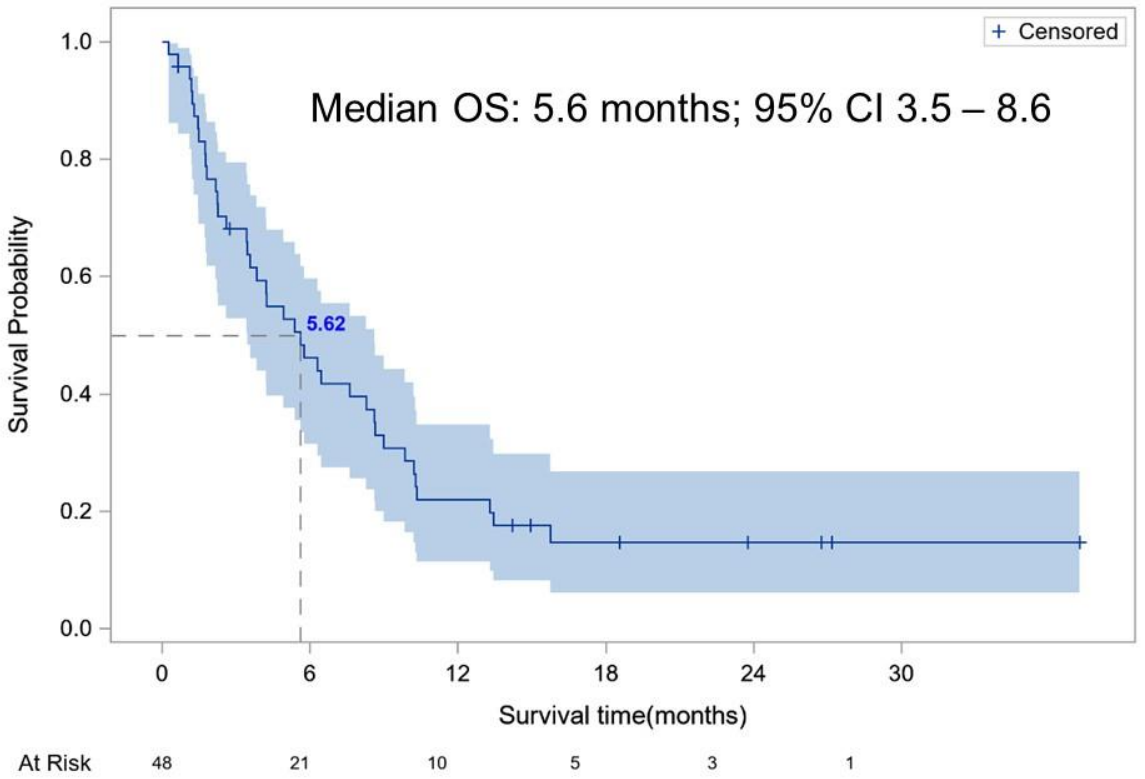


Non-L-Sarcoma (Group B): Survival

progression-free survival

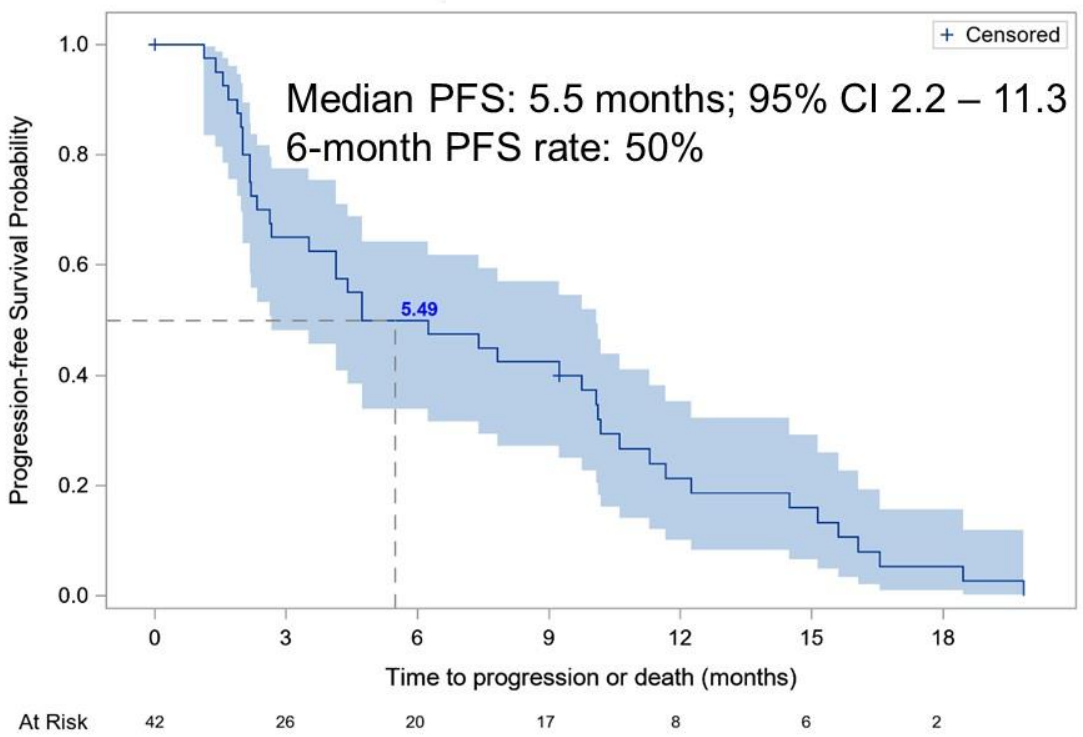


overall survival



L-Sarcoma (Group A): progression-free survival

Group A: overall



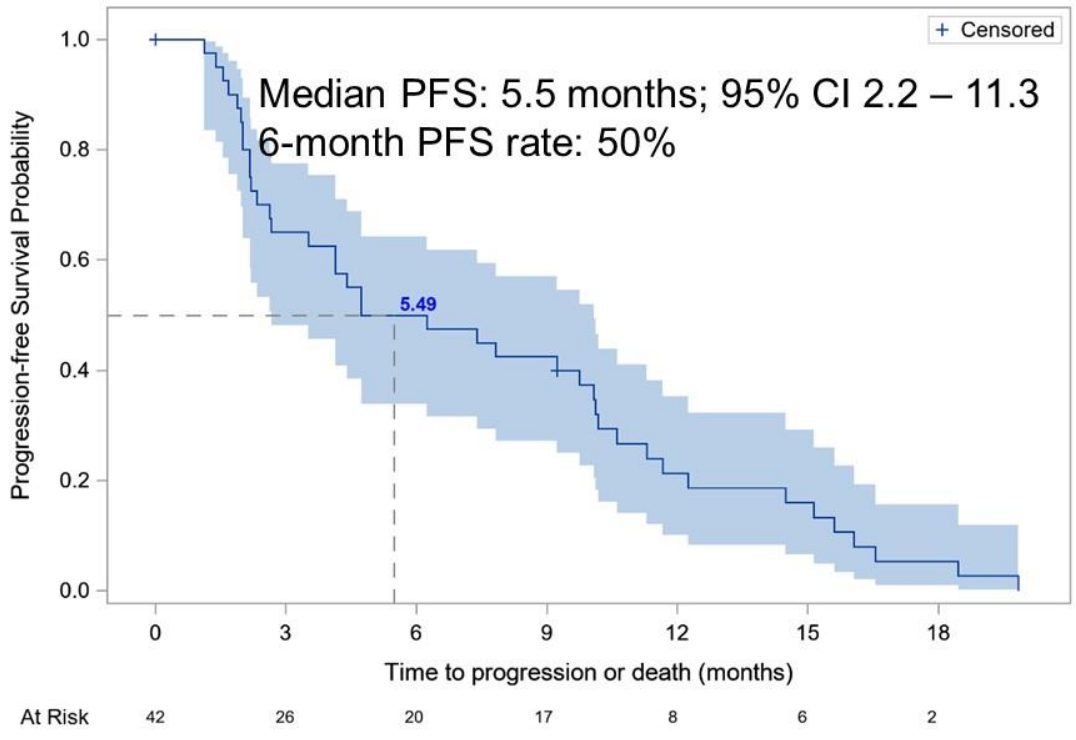
Statistical Design

combination insufficient, if PFSR6 ≤ 35%

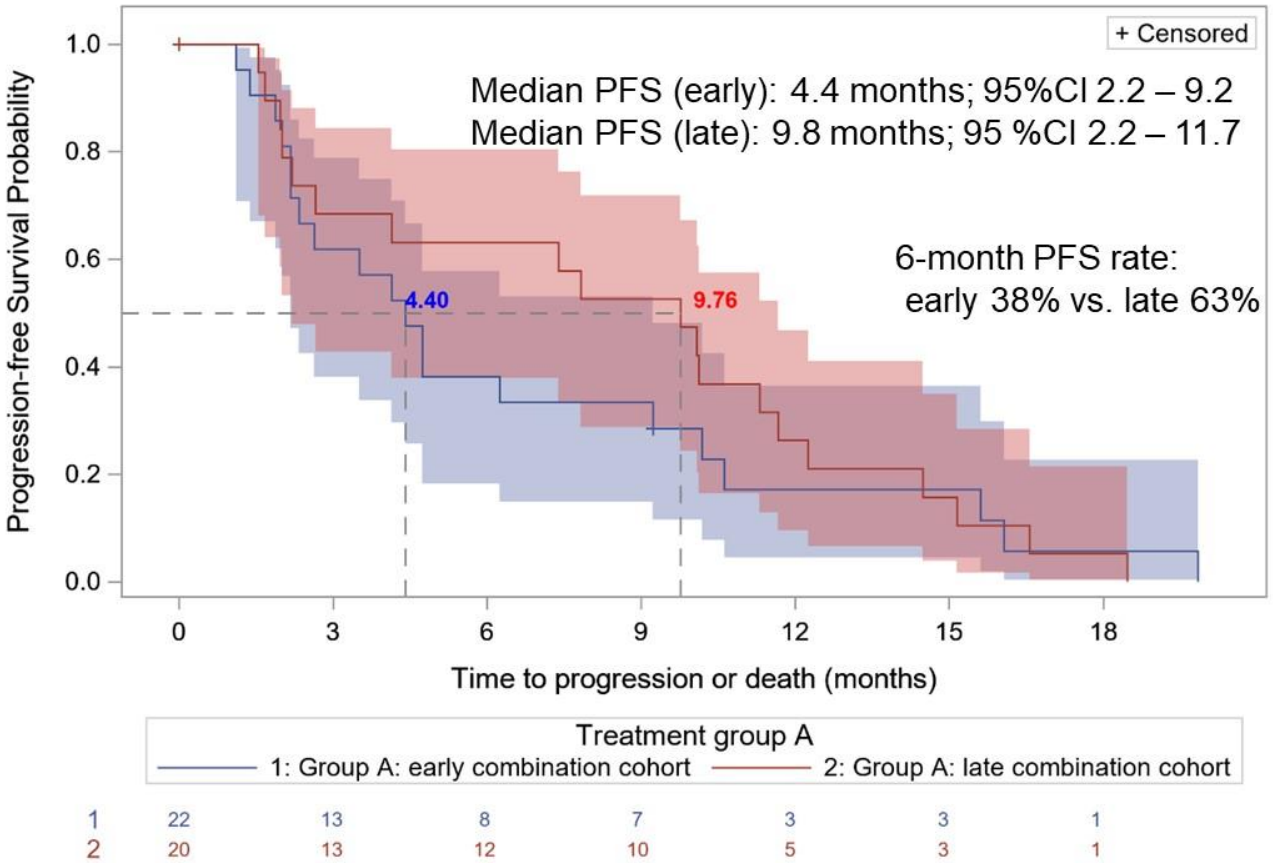
combination highly promising, if PFSR6 ≥ 55%

L-Sarcoma (Group A): progression-free survival

Group A: overall

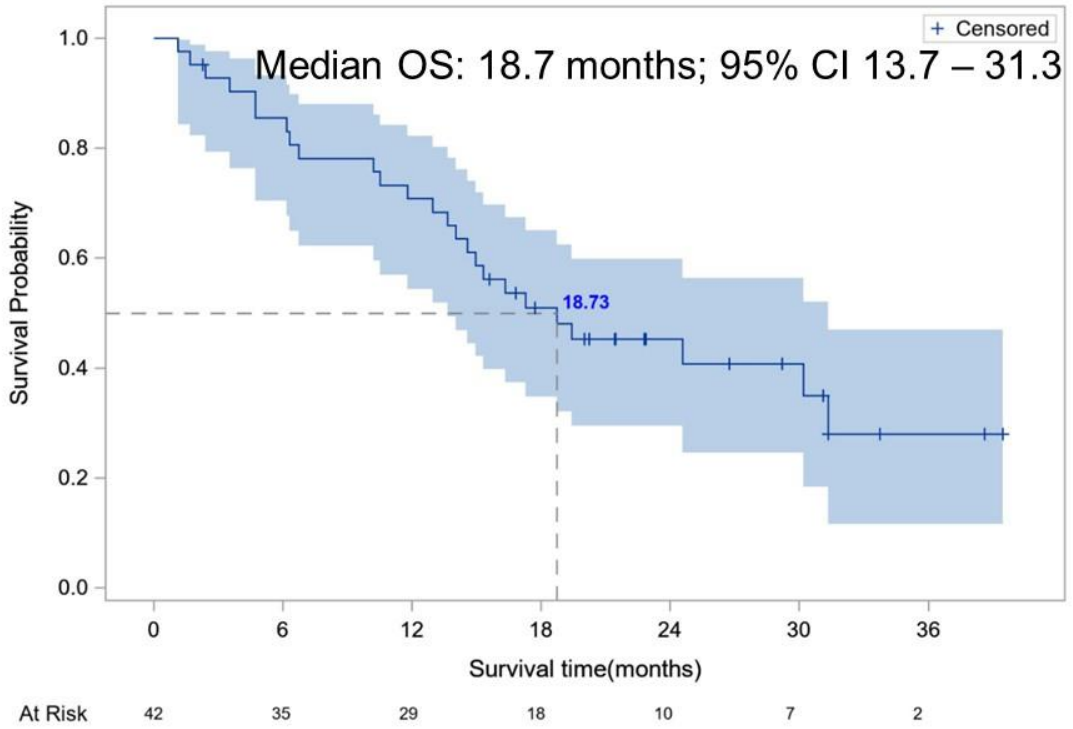


early combination vs. late combination

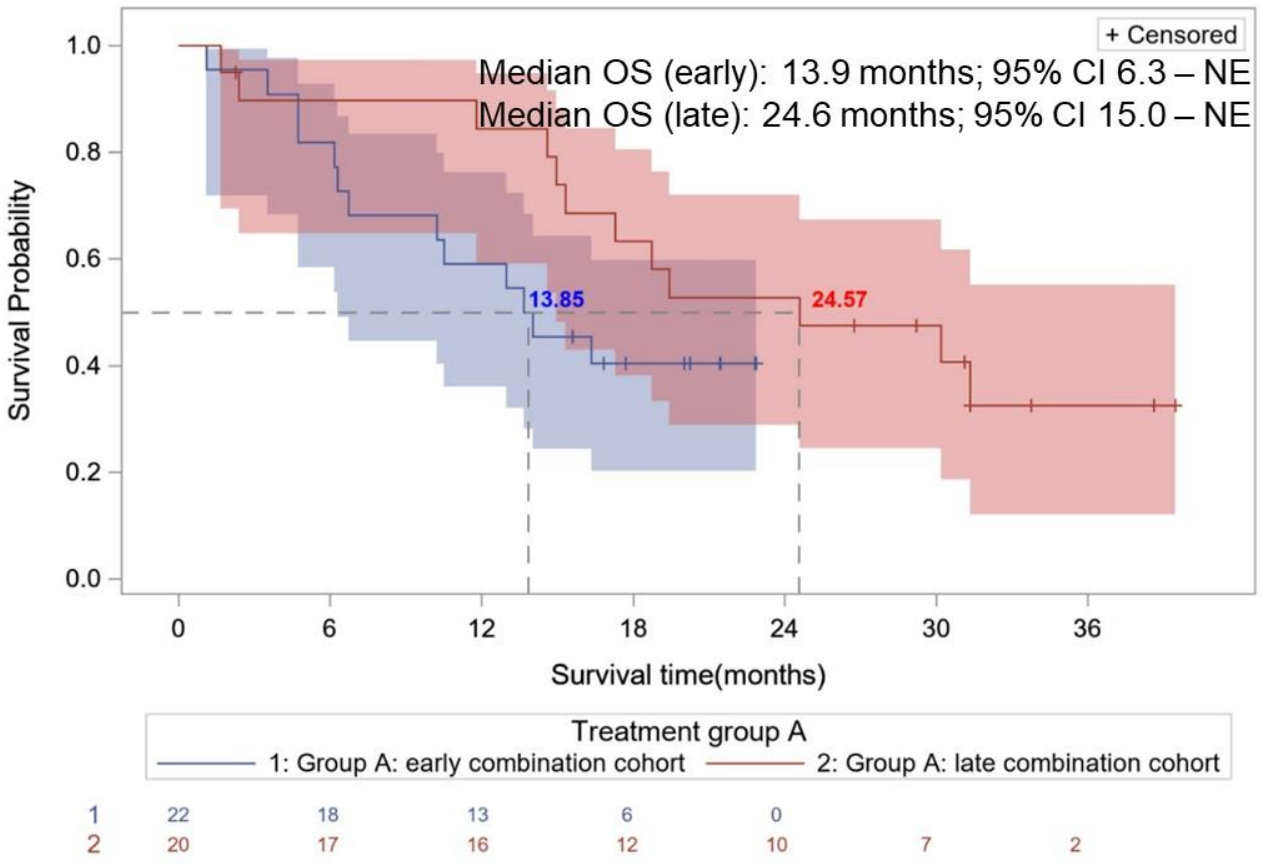


L-Sarcoma (Group A): overall survival

Group A: overall



early combination vs. late combination



Conclusions 1

- results in group B do not justify further investigation of trabectedin plus nivolumab in non-L-sarcomas.
- study confirms the preferential activity of trabectedin in patients with LMS and LS
- no new or unexpected toxicity signals

Conclusions 2

- the striking difference between ECC and LCC in terms of PFSR6, PFS and OS seen with the combination of trabectedin and nivolumab in L-Sarcomas could be explained by low numbers and other bias

Conclusions 3

- the striking difference between ECC and LCC in terms of PFSR6, PFS and OS seen with the combination of trabectedin and nivolumab in L-Sarcomas suggests synergistic activity in LCC and could be explained by increased immunogenicity resulting from pretreatment with trabectedin

- this may lead to new concepts in combining chemotherapy and immunotherapy in different tumor types

- solid confirmation would require a randomized trial

2023 ASCO ANNUAL MEETING

ImmunoSarc2: A Spanish Sarcoma Group (GEIS) phase Ib trial of doxorubicin and dacarbazine plus nivolumab in first line of advanced leiomyosarcoma

Javier Martin-Broto[1], Roberto Diaz-Beveridge[2], David Moura[1], Rafael Ramos[3], Javier Martinez-Trufero[4], Irene Carrasco[5], Antonio Lopez-Pousa[6], Enrique González[7], Antonio Gutierrez[3], Claudia Valverde[8], Josefina Cruz[9], Nadia Hindi[1]

1 Hospital Universitario Fundación Jiménez Díaz; 2 Hospital Universitari i Politècnic la Fe; 3 Hospital Universitari Son Espases; 4 Hospital Universitario Miguel Servet; 5 Hospital Universitario Virgen del Rocío; 6 Hospital de la Santa Creu i Sant Pau; 7 Hospital Universitario 12 de Octubre; 8 Hospital Universitari Vall d'Hebron; 9 Hospital Universitario de Canarias

PRESENTED BY: Dr. Javier Martin-Broto

Targeting Immunogenic Cell Death in Sarcoma

.- Immunogenic cell death (ICD) consists of a peculiar type of tumor cell death that is able to emit immunostimulatory signals eliciting an adaptive immune response.[1]

.- These signals, known as Damage-Associated Molecular Patterns (DAMPs), are released in a precise spatiotemporal configuration.

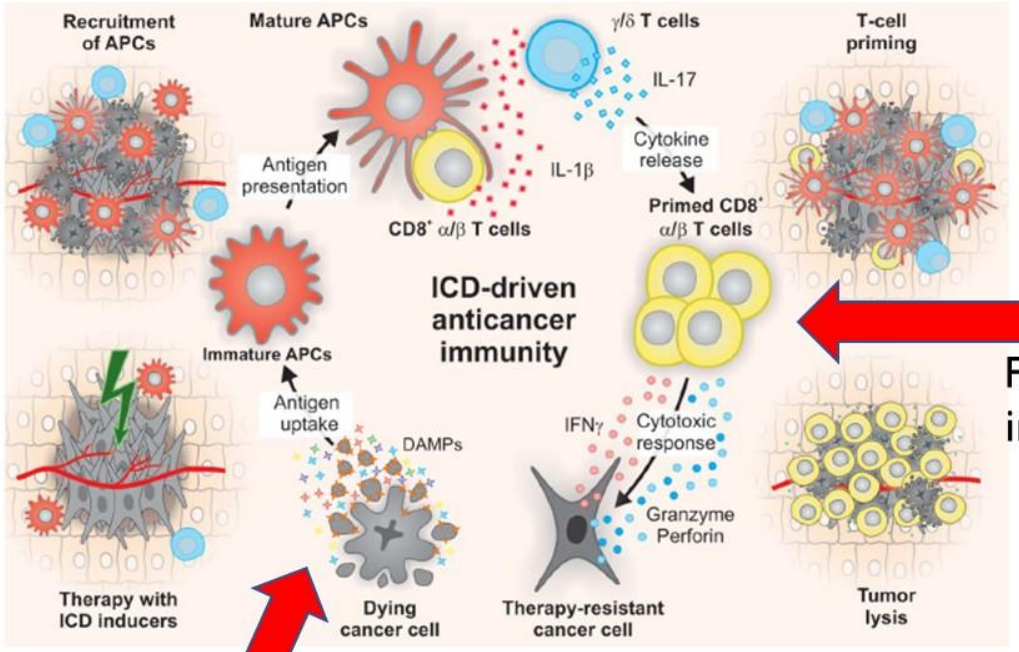
.- Doxorubicin (and other anthracyclines) showed to autonomously trigger ICD converting dying cancer cells into a vaccine

.- This property exhibited by doxorubicin is shared by a restricted lethal triggers

.- Some DAMPs induce robust immunostimulatory effects through Pattern Recognition Receptors expressed by immune cells: Calreticulin, ATP and HMGB1[2]

(1) J Exp Med. 2005 Dec 19;202(12):1691-701
(2) Oncoimmunology. 2014 Dec 13;3(9):e955691

Hypothesis: To enhance the Immune Response elicited by ICD



Oncoimmunology. 2014 13;3(9):e955691

PD1/PDL1 inhibitors

Anthracyclin-based CT

- ✓ Doxorubicin & Pembrolizumab was explored in a phase I/II treating advanced STS patients (n=37)[1]

Main outcomes:
- PR (22%); SD (59%); PD (19%)
- mPFS 8.1 months (95% CI 7.6-10.8)
- mOS 27.6 months (95% CI 18.7-NR)

- ✓ We hypothesized that the addition of anti-PD1 (Nivolumab) would increase efficacy of upfront Doxorubicin+DTIC in advanced LMS patients.

- ✓ Doxorubicin-DTIC achieved an ORR of 30.9% and superior mPFS and mOS in retrospective series (n=303) vs Doxorubicin alone in LMS patients.[2]

(1) JAMA Oncol. 2020 Nov 1;6(11):1778-1782.
(2) Cancer. 2020 Jun 1;126(11):2637-2647

IMMUNOSARC TRIAL cohort 7b

.- Phase Ib trial with 2 dose-levels: (3+3 design[1] with a minimum of 20 evaluable patients in RP2D)

- **Level 0**: Doxorubicin 75 mg/m^2/d d1+ DTIC 400 mg/m^2/d d1-2 + Nivolumab 360 mg on day 2/ 21d + GCSF
- **Level -1**: Doxorubicin 75 mg/m^2/d d1+ DTIC 400 mg/m^2/d d1-2 + Nivolumab 240 mg on day 2/ 21d + GCSF

.- After 6 cycles, Nivolumab/21d during 1 year as maintenance phase

.- Main Inclusion/Exclusion criteria:

- Anthracycline naïve; Advanced centrally confirmed LMS; ECOG 0-1; Measurable disease

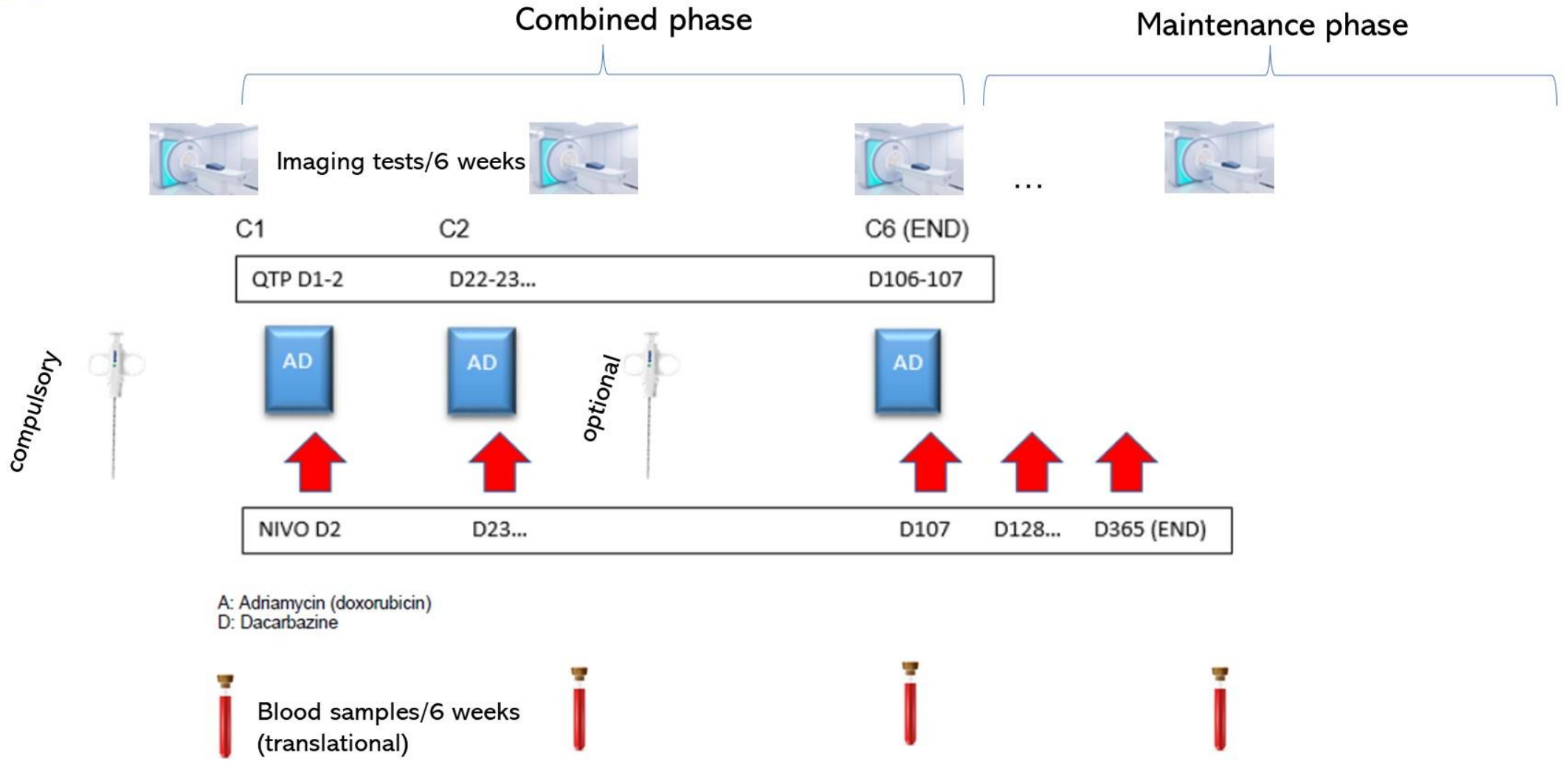
.- Main Endpoint: To determine the MTD/RP2D based on DLTs observed during the first 21-day cycle

.- Secondary Objectives: Safety profile (CTCAE 5.0); ORR (RECIST 1.1); mPFS; mOS; Translational

(1) Biometrics. 1989 Sep;45(3):925-37. PMID: 2790129

METHODS

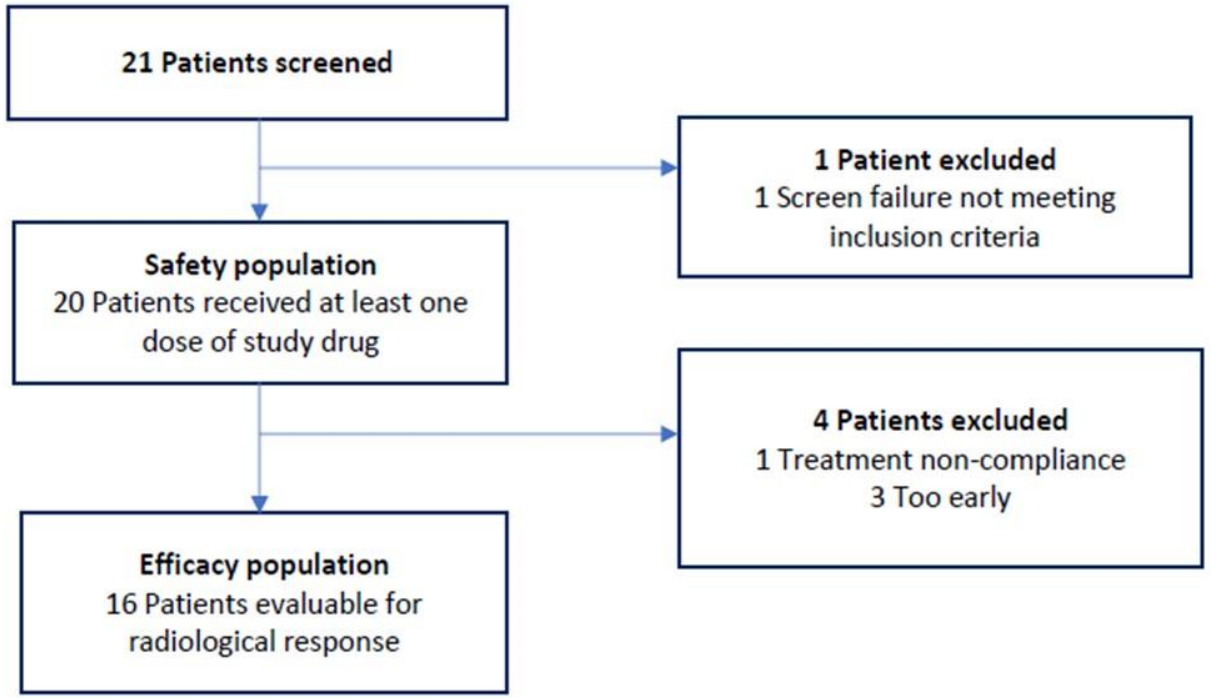
IMMUNOSARC TRIAL cohort 7b



RESULTS-1

Demographics

.- From Jan 2022 to Feb 2023, 20 were enrolled in 8 GEIS Hospitals



	Safety cohort N=20	Efficacy cohort N=16
Age	54 y (31-72)	52 (31-72)
Sex M/F	6 (30%)/14 (70%)	5 (31%)/11(69%)
ECOG 0/1	15 (75%)/5 (25%)	13 (81%)/3 (19%)
Primary Tumor Site Limbs Retroperitoneum Uterus Other	 4 (20%) 4 (20%) 9 (45%) 3 (15%)	 2 (12%) 4 (25%) 7 (44%) 3 (19%)
Staging at diagnosis Localized Locally Advanced Metastatic	 9 (45%) 1 (5%) 10 (50%)	 6 (37%) 1 (6%) 9 (56%)
Median MFI (range)	0.1 (0-78.7)	0.8 (0-78.7)
Median ∑ target les. Mean ∑ target les.		9.8 cm 12.7 cm

RESULTS-2

Toxicity Evaluation: TREAES (n=20, but 3 too early)

TREAES	Any grade	Grade 1-2	Grade 3	Grade 4	Grade 5
Anemia	10 (50.0%)	6 (30.0%)	4 (20.0%)	0	0
Neutropenia	8 (40.0%)	2 (10.0%)	3 (15.0%)	3 (15.0%)	0
Leukopenia	6 (30.0%)	3 (15.0%)	2 (10.0%)	1 (5.0%)	0
Thrombocytopenia	4 (20.0%)	3 (15.0%)	1 (5.0%)	0	0
Lymphocytosis	1 (5.0%)	1 (5.0%)	0	0	0
Febrile neutropenia	1 (5.0%)	0	1 (5.0%)	0	0
Fatigue	9 (45.0%)	8 (40.0%)	1 (5.0%)	0	0
Alopecia	8 (40.0%)	7 (35.0%)	1 (5.0%)	0	0
Nausea	7 (35.0%)	7 (35.0%)	0	0	0
Skin/nail alterations	4 (20.0%)	4 (20.0%)	0	0	0
ALT increased	4 (20.0%)	4 (20.0%)	0	0	0
Dysgeusia	3 (15.0%)	3 (15.0%)	0	0	0
Diarrhea	3 (15.0%)	3 (15.0%)	0	0	0
Constipation	3 (15.0%)	3 (15.0%)	0	0	0
Vomiting	2 (10.0%)	2 (10.0%)	0	0	0
Pain	2 (10.0%)	2 (10.0%)	0	0	0
Mucositis oral	2 (10.0%)	2 (10.0%)	0	0	0
Dry mouth	2 (10.0%)	2 (10.0%)	0	0	0
Blood bilirubin increased	2 (10.0%)	1 (5.0%)	1 (5.0%)	0	0
Anorexia	2 (10.0%)	2 (10.0%)	0	0	0
AST increased	2 (10.0%)	2 (10.0%)	0	0	0
Pneumonitis	1 (5.0%)	1 (5.0%)	0	0	0
GGT increased	1 (5.0%)	0	1 (5.0%)	0	0
Fever	1 (5.0%)	1 (5.0%)	0	0	0

No DLTs were reported. No toxic deaths. 2 drug-related SAEs (hospitalization): G2 fever and G3 febrile neutropenia.
1 nivolumab-related event: G1 (asymptomatic) pneumonitis.

Efficacy Variables

.- Median follow-up: 8 months (2-12)

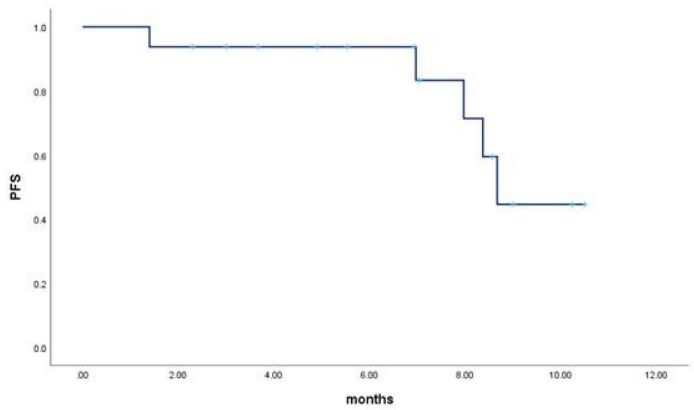
.- #Cycles (combo): 94. Median: 6 (1-6)

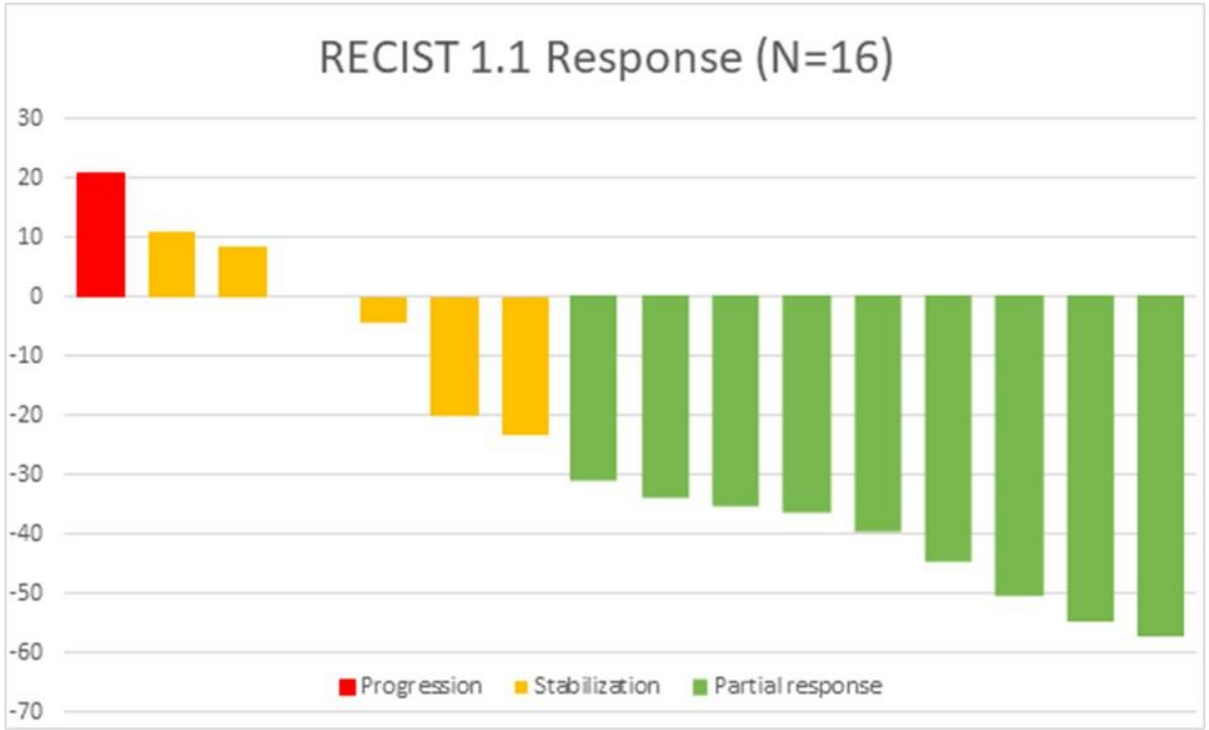
.- ORR from 16 evaluable patients:

9 PR (56.2%); 6 SD (37.5%); 1 PD (6.3%)

.- mPFS 8.67 months (95% CI: 7.96-9.37)

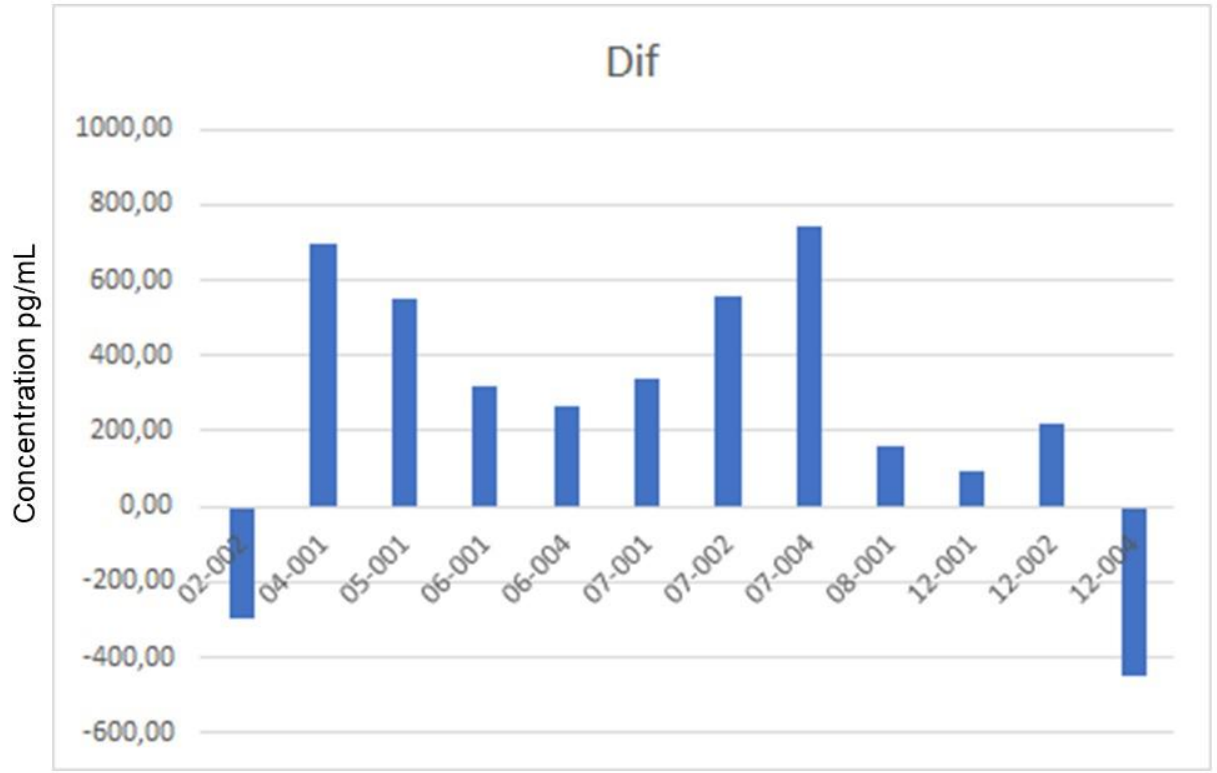
.- Median to response: 1.7 months (95% CI1.1-9)





RESULTS-4

Difference in serum HMGB1 expression [Week 6]-[Baseline]



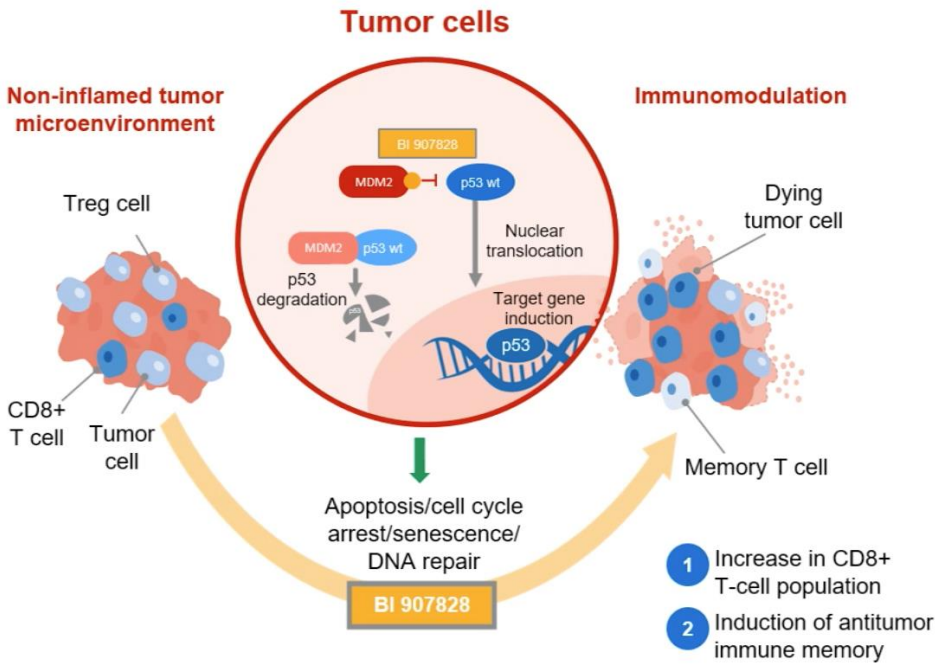
Factor	Median PFS (CI 95%)	P
Age		0.19
0-52 years	8.4 (7.7-9)	
> 52 years	NR	
Sex		0.094
Male	NR	
Female	8.4 (7.7-9.1)	
Primary site		0.42
Limbs	NR	
Retroperit.	8 (NA)	
Uterus	8.4 (5.5-11.2)	
Other	NR	
MFI		0.32
0-12 months	8.7 (7.7-9.6)	
> 12 months	NR	
HMGB1 change		**0.029**
< 11.6%	**8.4 (6.1-10.6)**	
≥ 11.6%	**NR**	
ECOG		0.53
0	8.4(NA)	
1	8.7 (NA)	

Conclusions

- The combination of Doxorubicin 75 mg/m^2/d d1+ DTIC 400 mg/m^2/d d1-2 + Nivolumab 360 mg on day2 + GCSF every 21 days (RP2D) is feasible and well tolerated.
- The preliminary activity is encouraging (seemingly improving historical efficacy/outcomes) as systemic upfront line in advanced LMS patients.
- A significant correlation is found between % increase of HMGB1 and a longer PFS, probably indicating an activation of ICD.
- Future designs will be focused on the improvement of the maintenance strategy.

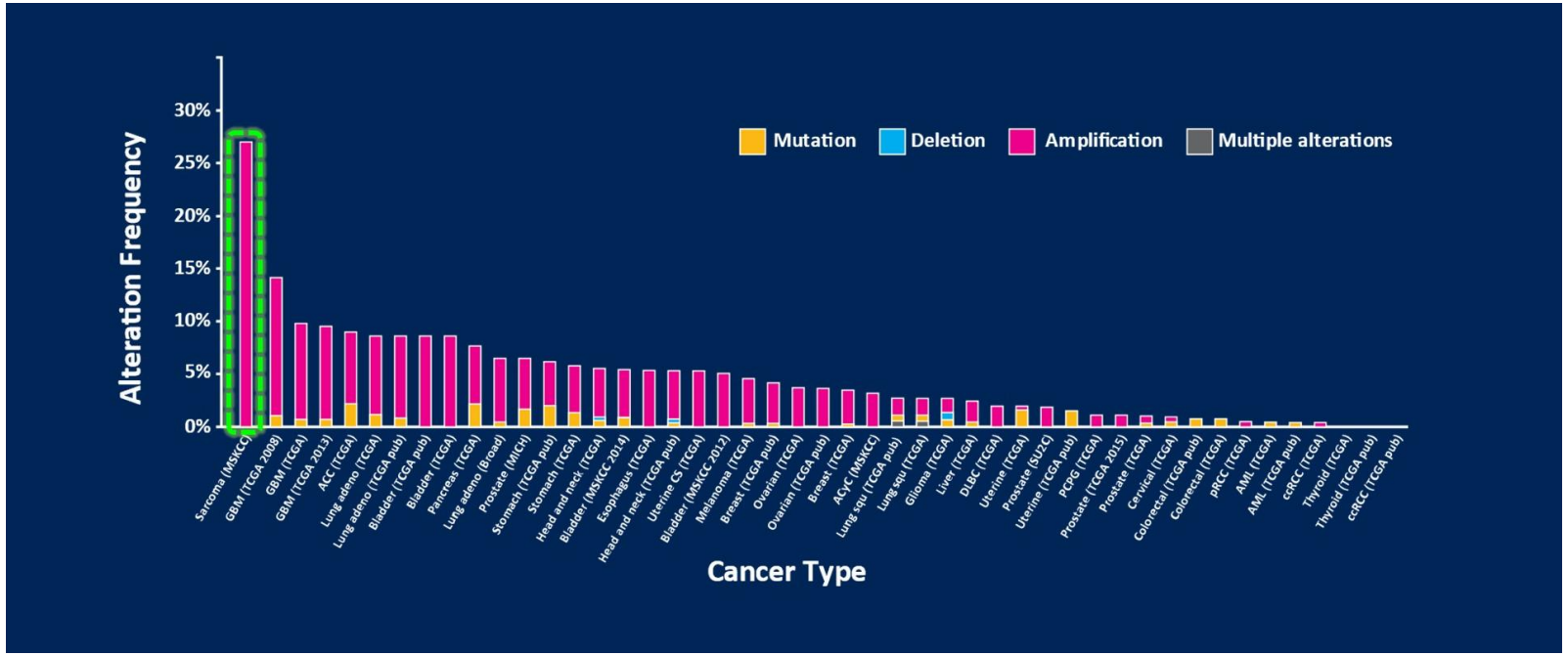
MDM2-gerichtete Therapie bei MDM2-amplifizierten dedifferenziierten Liposarkomen (DDLPS) >2 L

- MDM2 mediates loss of WT p53 function
- Blocking the MDM2–p53 interaction to restore wild-type p53 function is therefore a potential therapeutic strategy in cancers with wild-type or functional p53
- While varying by tumour type, overall approximately 5–7% of tumours display *MDM2* amplifications



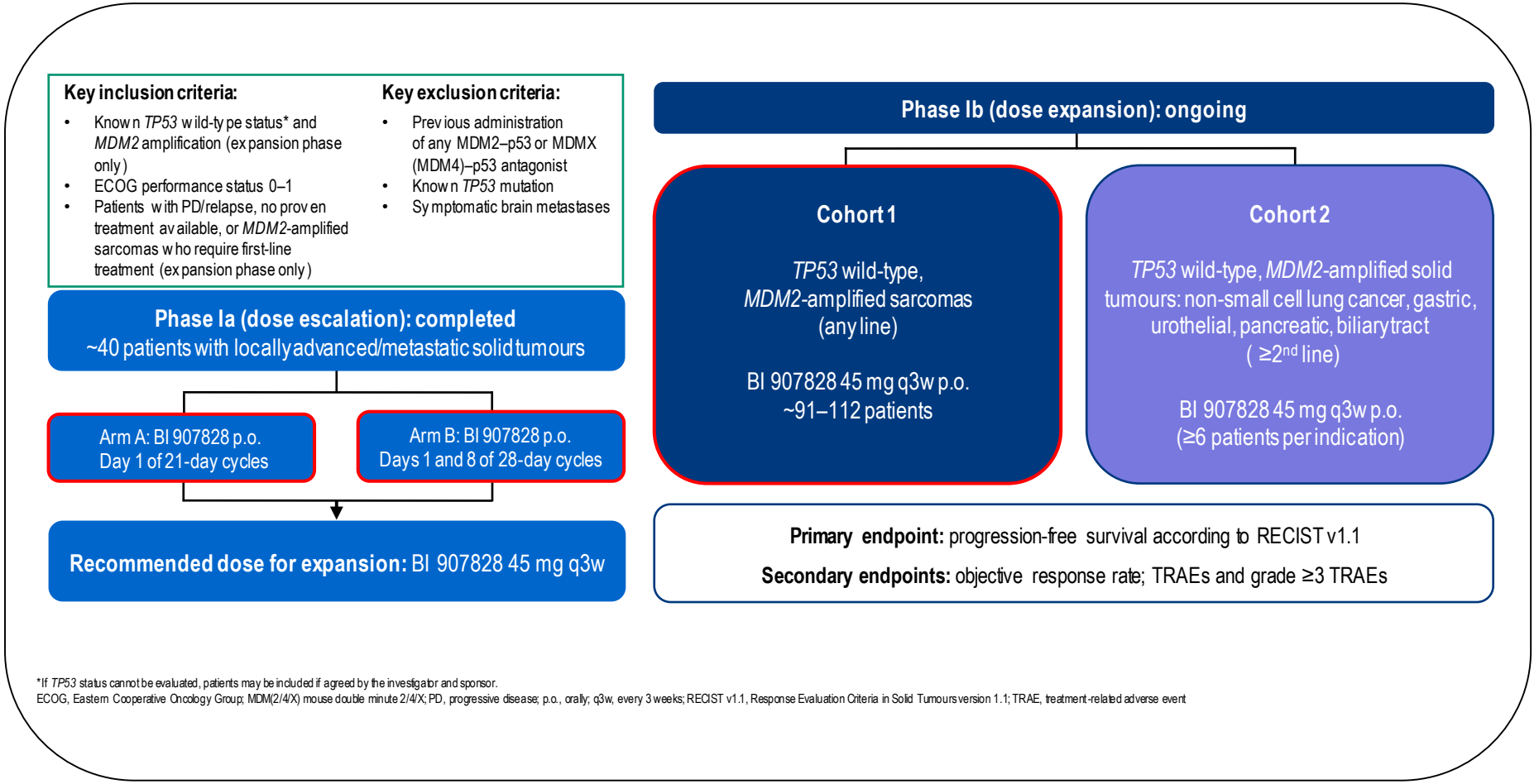
Patrick Schöffski, ASCO 2023

Häufigkeit von MDM2-Amplifikation und MDM2-Alterationen



Gounder, CTOS 2022

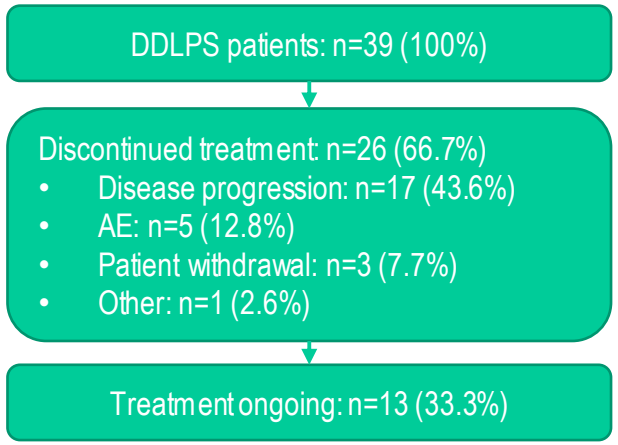
Phase I (NCT03449381; 1403-0001) dose escalation and dose expansion study design – DDLPS analysis



*If *TP53* status cannot be evaluated, patients may be included if agreed by the investigator and sponsor.
ECOG, Eastern Cooperative Oncology Group; MDM(2/4/X) mouse double minute 2/4/X; PD, progressive disease; p.o., orally; q3w, every 3 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1; TRAE, treatment-related adverse event

Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, Chicago, IL, USA, June 2–6, 2023
*Corresponding author email address: patricia.lorusso@yale.edu

Baseline characteristics DDLPS patients



Baseline patient characteristics	All patients (N=107)	DDLPS patients (n=39)
Mean age, years (range)	57 (19–83)	58.4 (36–76)
Male, n (%)	59 (55.1)	23 (59.0)
Ethnicity, n (%)		
Caucasian	75 (70.1)	26 (66.7)
Asian	24 (22.4)	10 (25.6)
Black/African American	3 (2.8)	1 (2.6)
Missing	5 (4.7)	2 (5.1)
ECOG performance status, n (%)*		
0	63 (58.9)	22 (56.4)
1	43 (40.2)	16 (41.0)
Prior lines of systemic therapies, median (range)	2 (0–11)	2 (0–8)

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Safety and adverse events in patients with DDLPS

AEs, n (%)	DDLPS patients (n=39)	
Any-grade AEs	37 (94.9)	
Grade ≥3 AEs	22 (56.4)	
Any-grade TRAEs	35 (89.7)	
Grade ≥3 TRAEs	14 (35.9)	
Serious AEs (any-cause)	14 (35.9)	
AEs leading to dose reduction/discontinuation	6/2 (15.4/5.1)	
Most common TRAEs	**Any grade**	**Grade ≥3**
Nausea	30 (76.9)	2 (5.1)
Fatigue	20 (51.3)	2 (5.1)
Vomiting	18 (46.2)	1 (2.6)
Decreased appetite	13 (33.3)	1 (2.6)
Diarrhoea	11 (28.2)	0 (0.0)
Thrombocytopenia	11 (28.2)	8 (20.5)
Anaemia	10 (25.6)	4 (10.3)
Neutropenia	9 (23.1)	3 (7.7)

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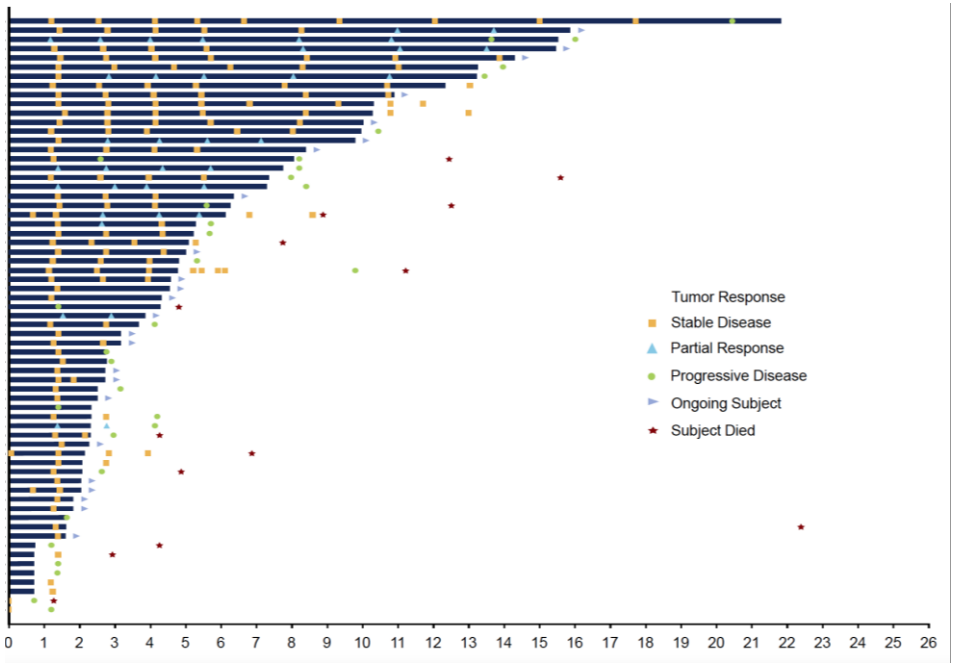
Preliminary efficacy in patients with DDLPS

Response, n (%)	Evaluable DDLPS patients (n=36)
Objective response	5 (13.9)
Complete response	0 (0.0)
Partial response	5 (13.9)
Stable disease	27 (75.0)
Unconfirmed CR/PR	2 (5.6)
Disease control rate	32 (88.9)
Progressive disease	4 (11.1)



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Gemeinschaftsklinikum Mittelrhein

Zusammenfassung

Angiosarkome:

- Cabozantinib / Nivolumab als 2. Linie nach Paclitaxel

Hohe Wirksamkeit von ICB mit Chemotherapie:

- NitraSarc: Trabectedin plus Nivolumab ab 2. Linie
- Doxorubicin / Dacarbacin / Nivolumab in 1. Linie bei LMS

Dedifferenzierte Liposarkome:

- MDM2 neues therapeutisch angehbares hochwirksames Target

Gemeinschaftsklinikum Mittelrhein gGmbH

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