Neuigkeiten rund um das Multiple Myelom

Prof. Dr. med. Markus Munder
III. Medizinische Klinik & Poliklinik
Hämatologie, Internistische Onkologie & Pneumologie
Universitätsmedizin Mainz

28.01.2021

MM: Zulassung neuer Substanzen und Kombinationen

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2004	2007	2008	2013	2015	2016	2017	2018	2019	2020	2021
Bortezomib	**Lena-lidomid**	**Thali-domid**	**Poma-lidomid**	**Carfilzomib** **Panobinostat**	**Daratumumab** **Elotuzumab** **Ixazomib**		***Deno-sumab***		**Isa-tuximab** **Belanta-mab**	
Vd	**Rd** **MPR**	**VMP** **MPT**	**PomD** **Vd** **VTd**	**Rd** **KRd** **PanVD**	**D** **ERd** **IRd** **Kd**	**DRd** **DVd** **R-Maint**	**DVMP**	**VRd** **DRd** **PVd** **EPd**	**D-VTD** **Isa-PomD** **Belan-tamab**	**DKd**

PROTEASOMEN-INHIBITOR

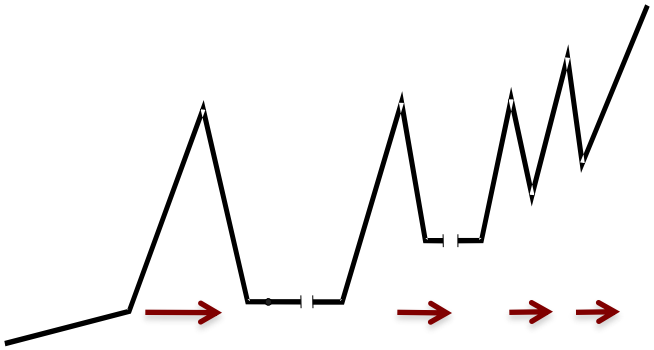
IMMUNMODULATORISCHE SUBSTANZ (IMID)

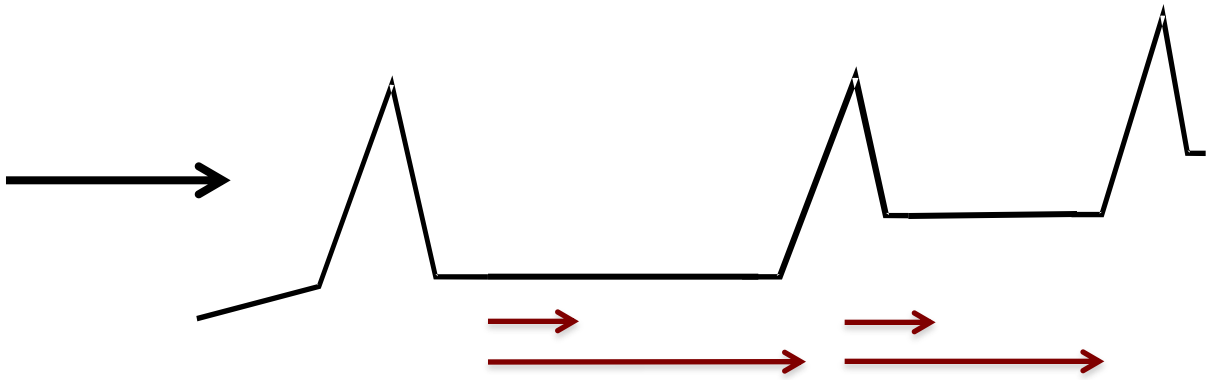
HDAC-INHIBITOR

MONOKLONALER ANTIKÖRPER

ANTIKÖRPER-KONJUGAT (ADC)

MM: Zulassung neuer Substanzen und Kombinationen





Behandlungssequenzen 2021

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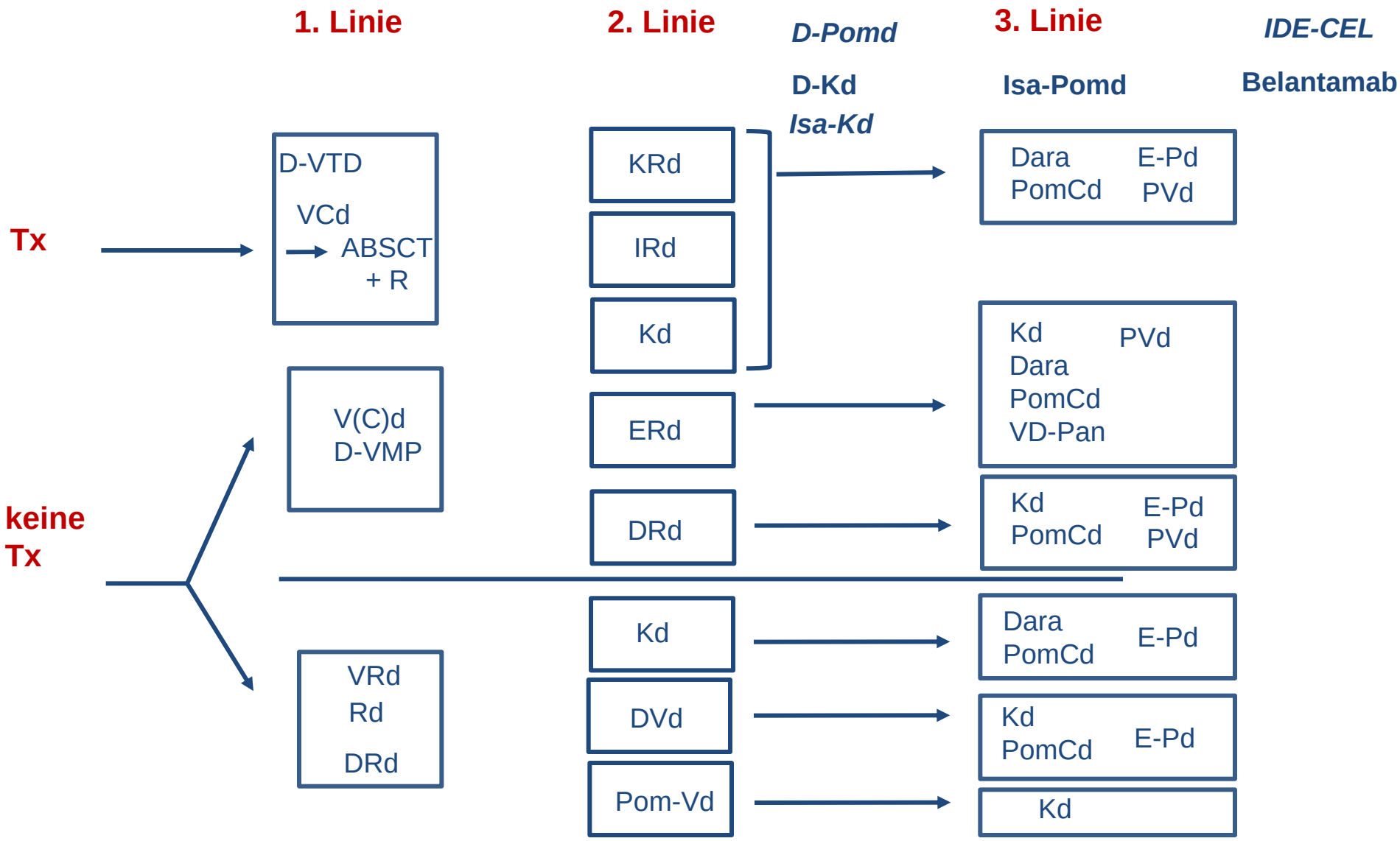

AGENDA

- Erstlinie
- Rezidiv
  - Lenalidomid – Refraktärität
  - Neue Substanzen
  - Immuntherapie
    - Immunkonjugate
    - CAR-T
    - Bispezifische Ak

AGENDA

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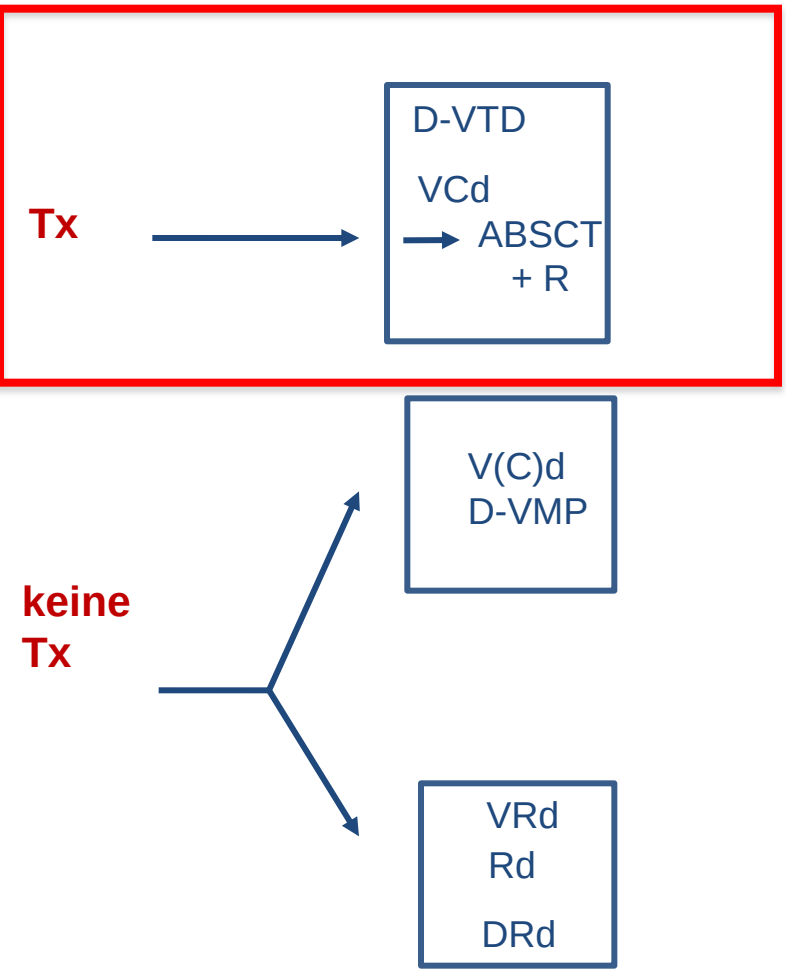
  - Lenalidomid – Refraktärität
  - Neue Substanzen
  - Immuntherapie
    - Immunkonjugate
    - CAR-T
    - Bispezifische Ak

Behandlungssequenzen

1. Linie



Transplantation in Erstlinie ?

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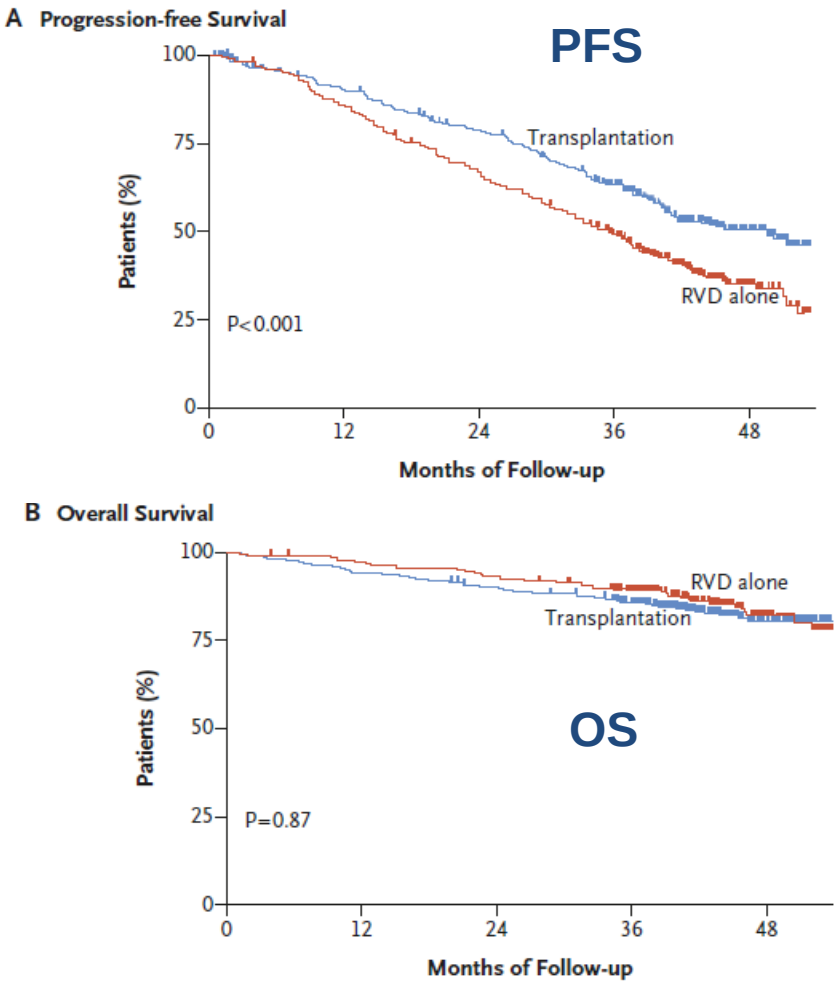
IFM2009: VRD +/- ASCT

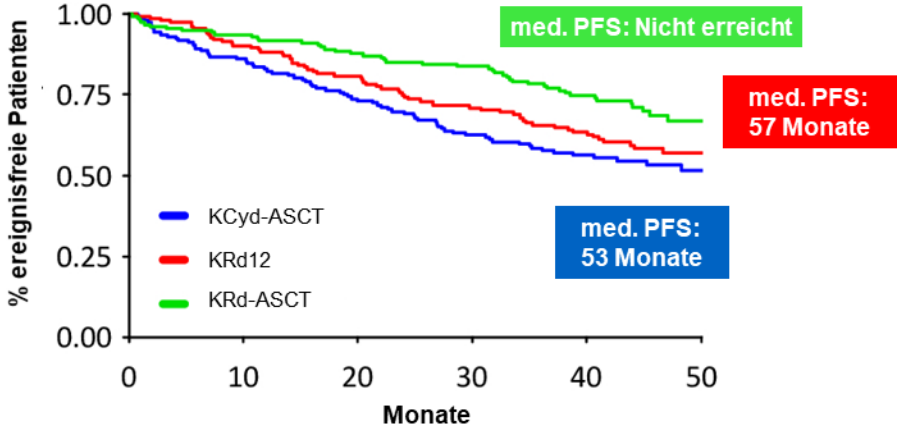


Attal M et al. *N Engl J Med. 2017.* 376: 1311-1320.

ASH 2020

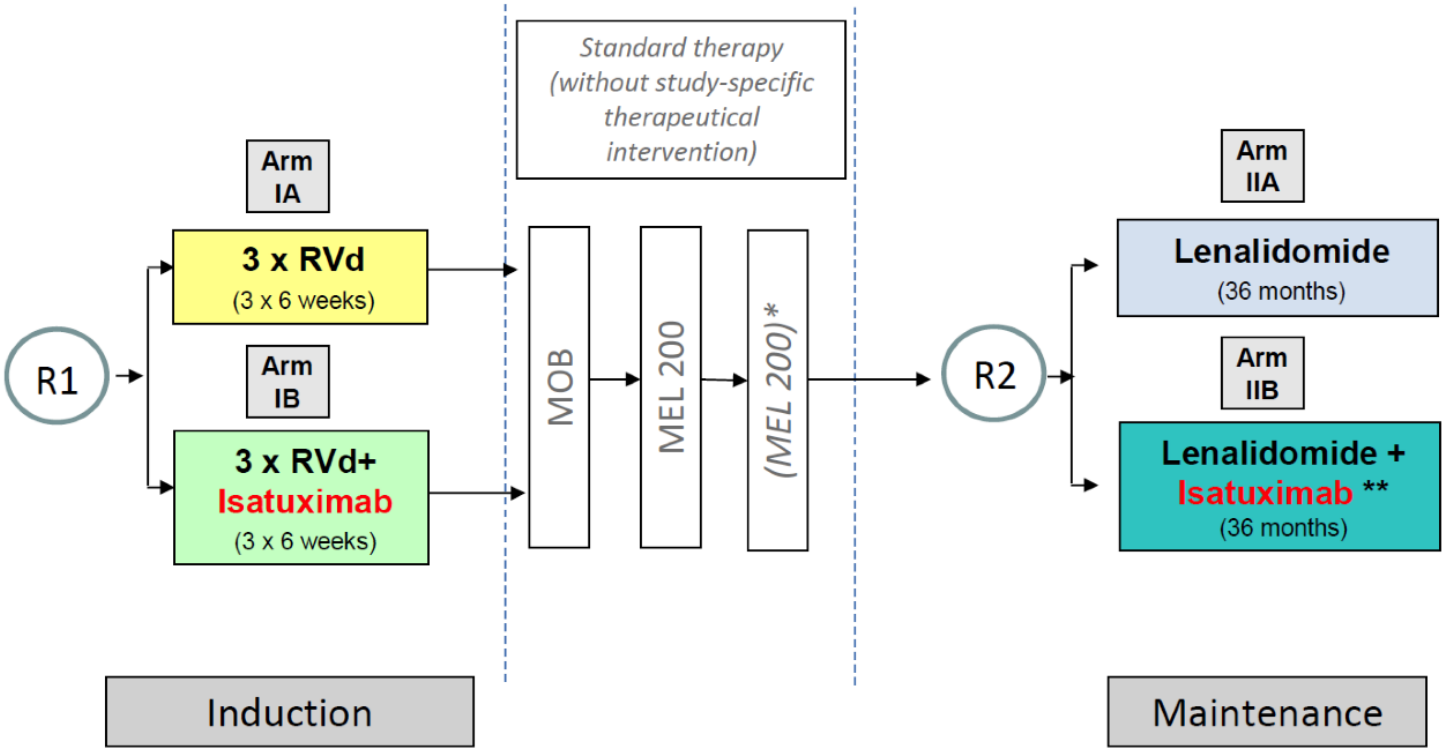
FORTE:

KRD +/- ASCT



Gay F M et al. *ASH 2020* abstract 141

Therapiekonzepte
Erstlinie : GMMG HD7



R1 = 1st randomization (at study inclusion); R2 = 2nd randomization (prior to maintenance)

* decision for 2nd high dose therapy response-adapted (in case no CR)

*** Lenalidomide/Isatuximab for 36 months (thereafter, continuation of lenalidomide recommended until PD)*

Quelle: German Speaking Myeloma Multicenter Group, GMMG, am Universitätsklinikum Heidelberg, Med. Klinik V

GRIFFIN Studie: Dara-VRd vs. VRd

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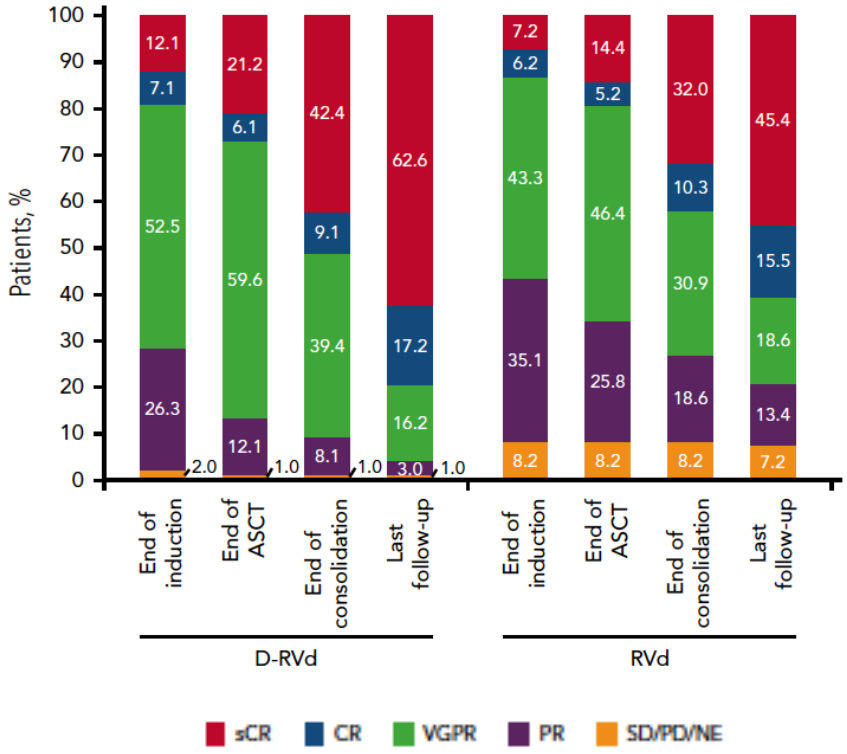
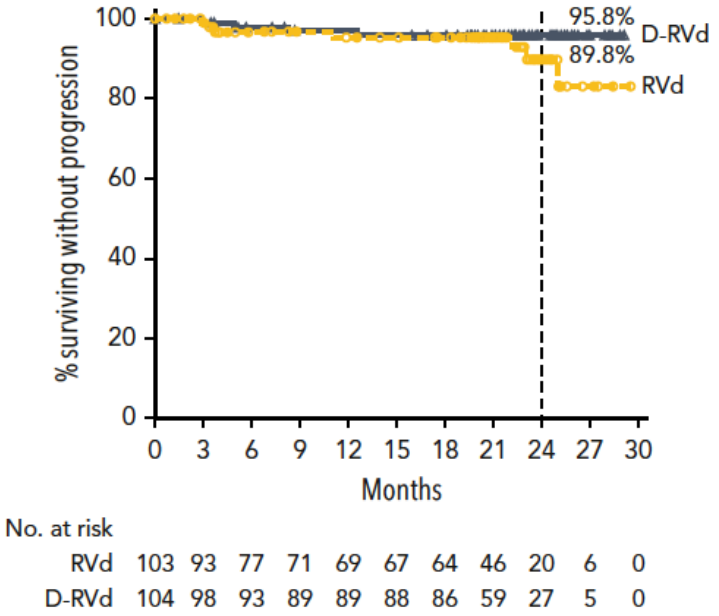
ORR



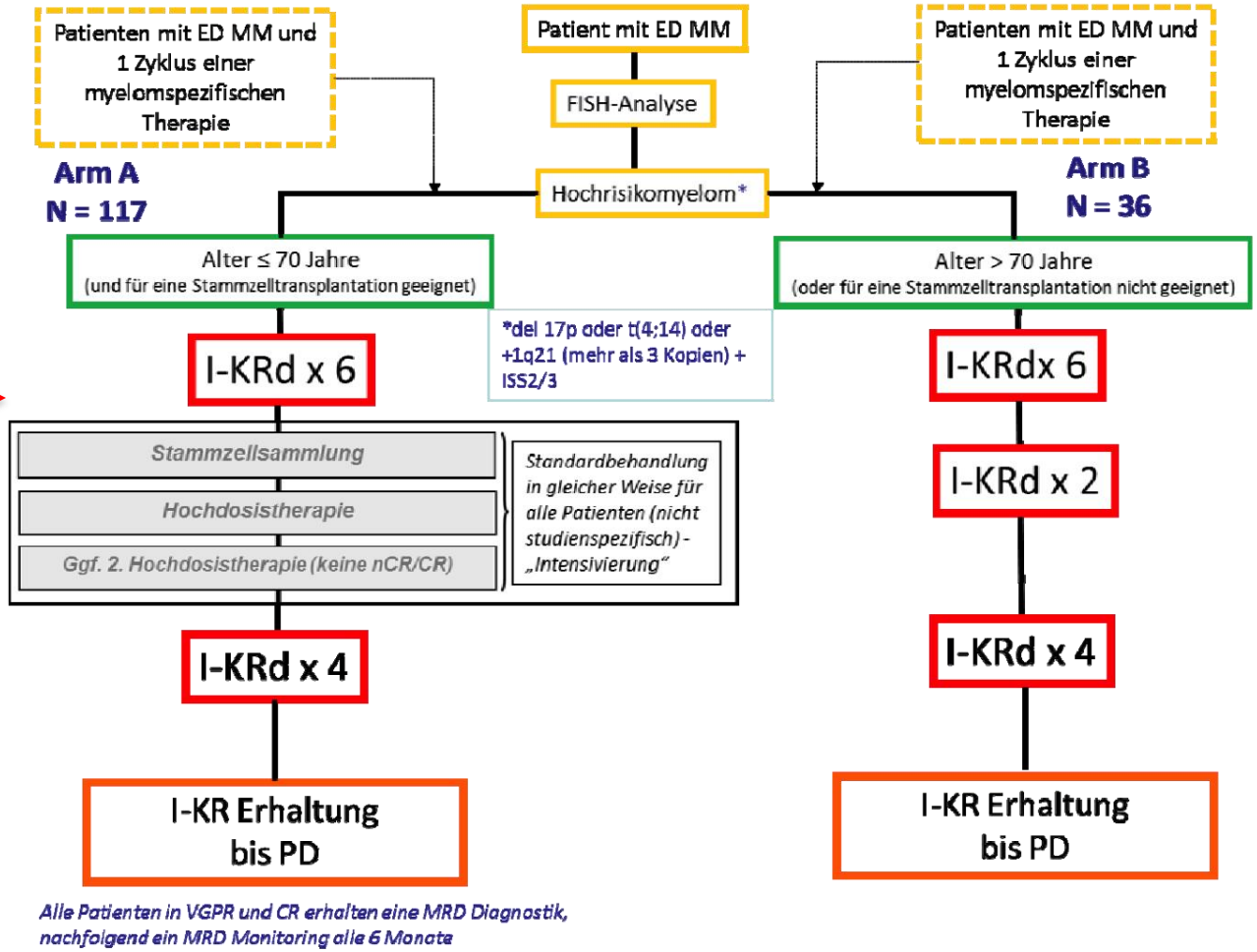
PFS



Vorhees et al., *Blood* 2020; 136:936-945

CONCEPT - Studie

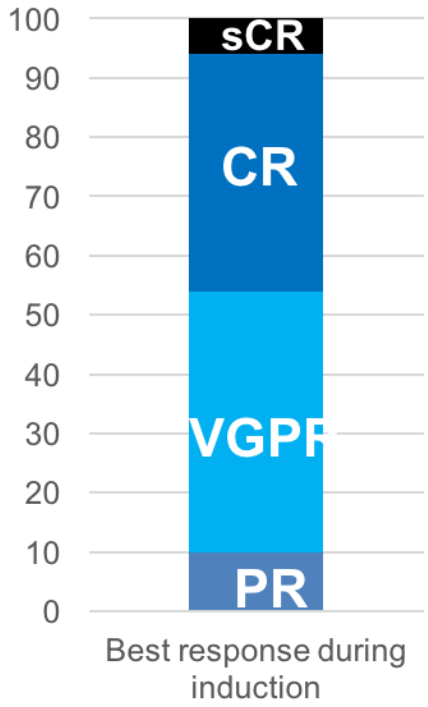
Interim Analyse EHA2020



EHA 2020

All evaluable patients: n = 50

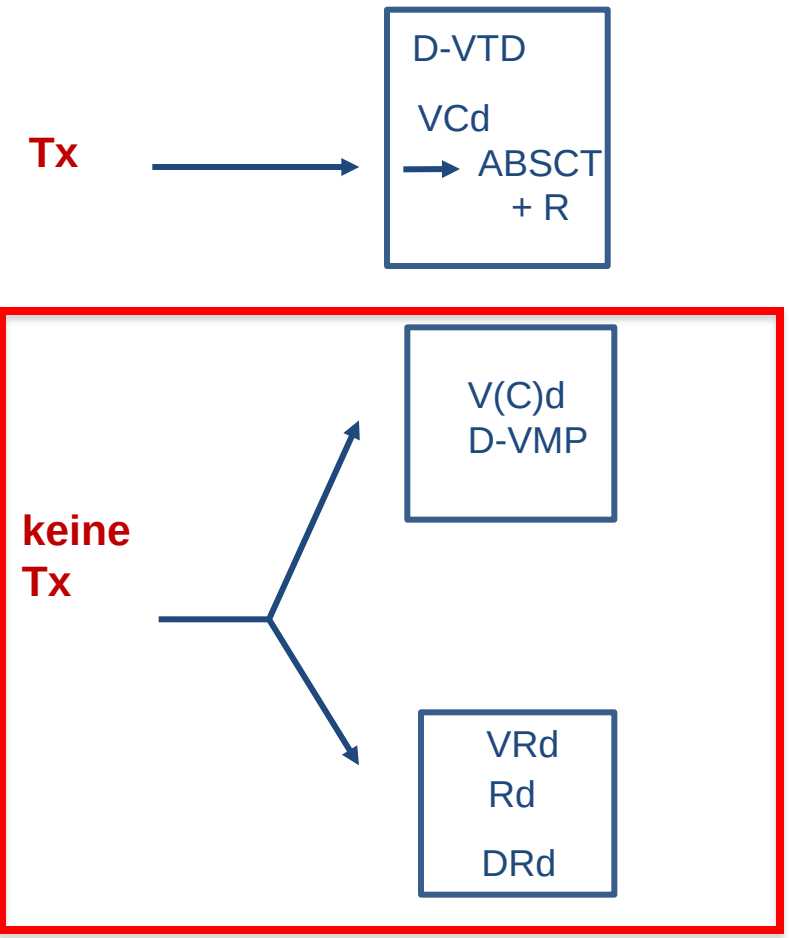
- **Overall response rate (ORR, ≥ PR): 100%**
- **≥ VGPR : 90%; CR/sCR: 46%**
  - Arm A: 41/46 ≥ VGPR
  - Arm B: all (n = 4) VGPR
- **Arm A: MRD-assessment in 33 patients during induction**
  - 20 patients MRD negative
  - 11 patients MRD positive
  - 2 not assessable



Weisel K. et al. EHA 2020. P420-5.

Behandlungssequenzen

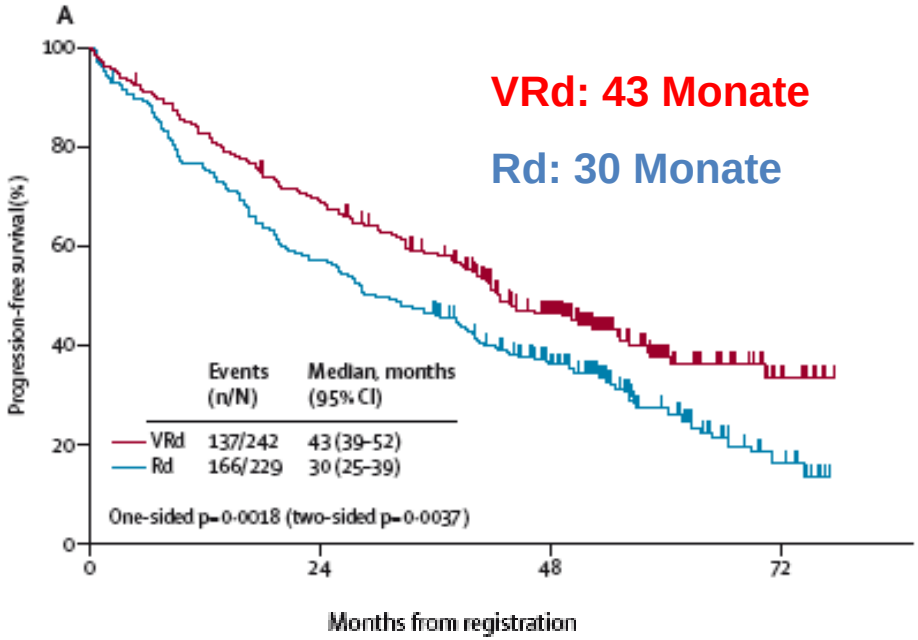
1. Linie



Erstlinie non Tx

SWOG S0777: Rd vs. VRd

PFS



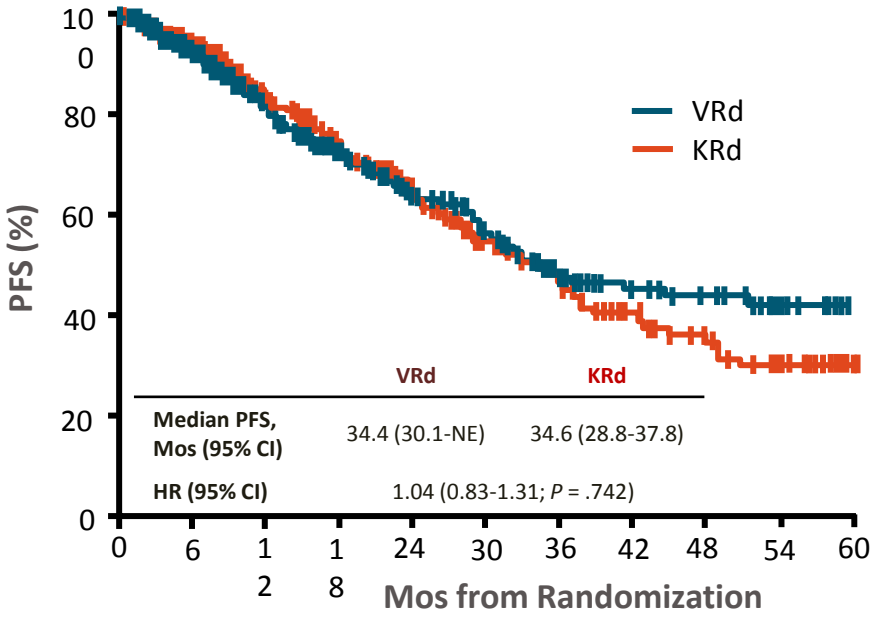
VRd: 43 Monate

Rd: 30 Monate

Durie et al. *Lancet* 2017; 389:519-527

Endurance Studie: VRd vs. KRd

PFS



Kumar et al., ASCO 2020; Abstract LBA3.

ASH 2020

TOURMALINE MM2 Studie: Ixa-Rd vs. Rd

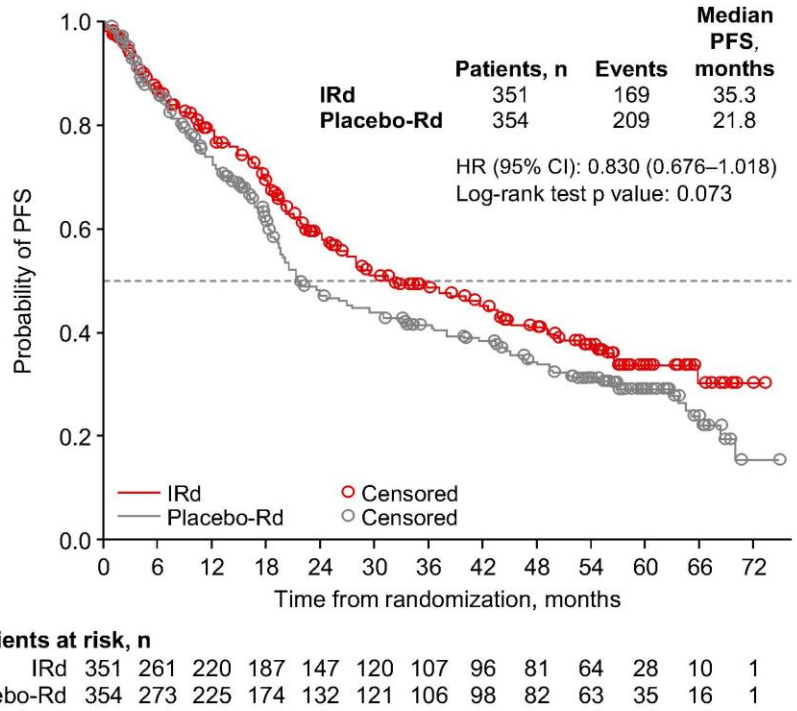


Table. PFS in prespecified subgroups, response rates, and other secondary outcomes in the ITT population

	IRd (N=351)	Placebo-Rd (N=354)		
PFS in prespecified subgroups, months			HR (95% CI)	p value
Expanded high-risk cytogenetics	23.8	18.0	0.690 (0.506–0.941)	0.019
Age <75 years	41.4	26.2	0.799 (0.608–1.049)	0.106
CrCl >60mL/min	31.8	30.8	0.992 (0.754–1.305)	0.955
Best confirmed response, %			OR (95% CI)	p value
ORR	82.1	79.7	1.16 (0.79–1.70)	0.436
CR/sCR	25.6	14.1	2.10 (1.43–3.09)	<0.001
≥VGPR	63.0	47.7	1.87 (1.38–2.53)	<0.001
Secondary outcomes, months			HR (95% CI)	p value
TTR	1.0	1.9	1.402 (1.185–1.659)	<0.001
TTP	45.8	26.8	0.738 (0.589–0.925)	0.008

OR, odds ratio; sCR, stringent complete response; VGPR, very good partial response

Facon et al., ASH2020; Abstract 551

Erstlinie non Tx

MAIA Studie: DRd vs. Rd

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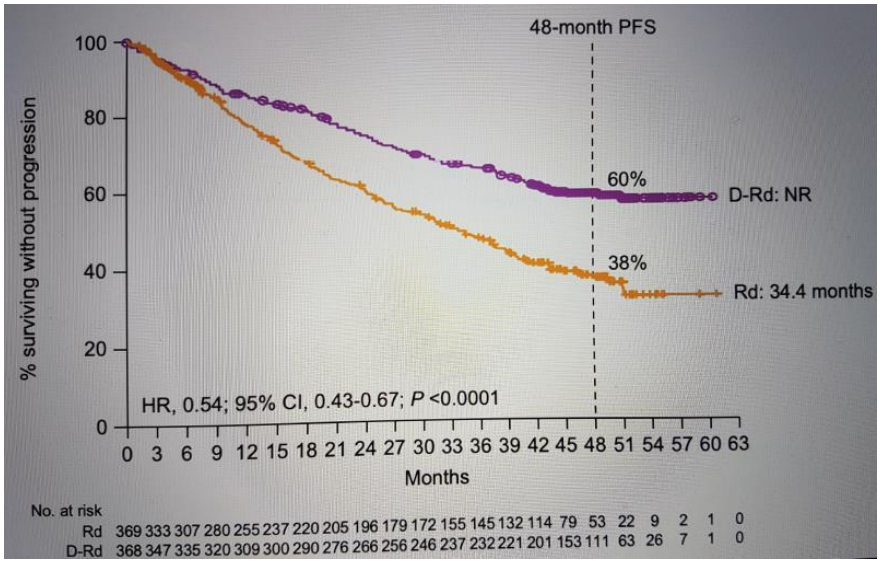
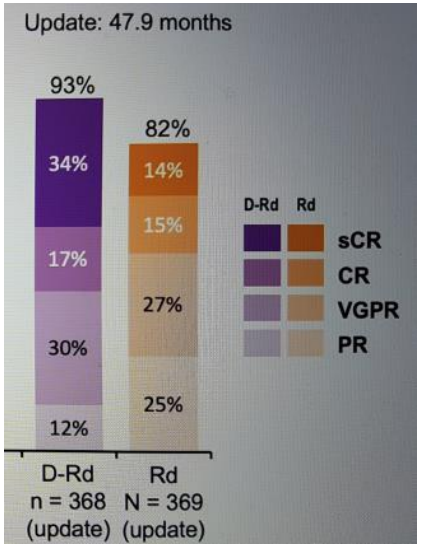
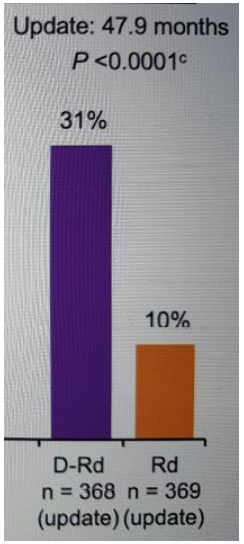
PFS



ORR



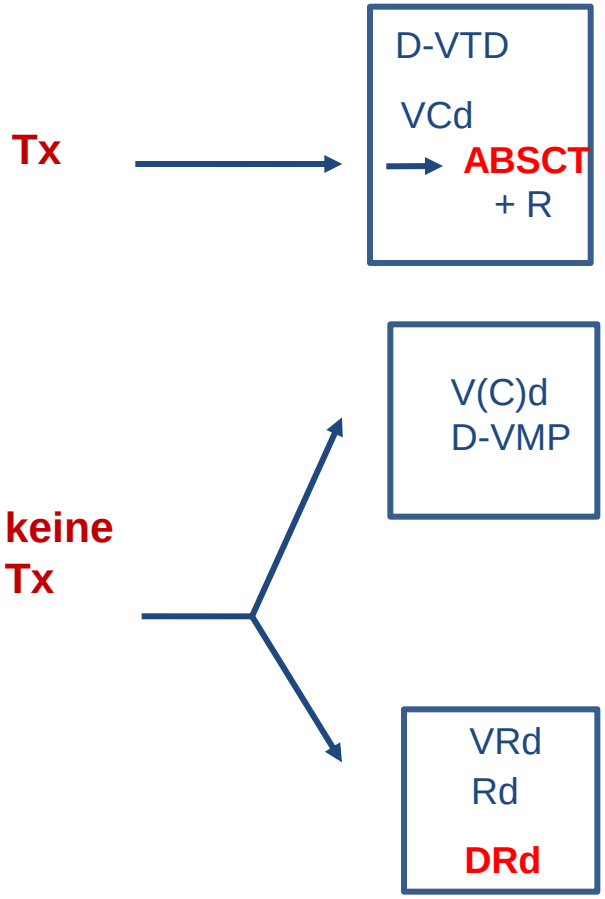
MRD neg



Kumar et al., ASH 2020; Abstract 2276

Behandlungssequenzen

1. Linie



AGENDA

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- **Rezidiv**
  - **Lenalidomid – Refraktärität**
  - Neue Substanzen
  - Immuntherapie
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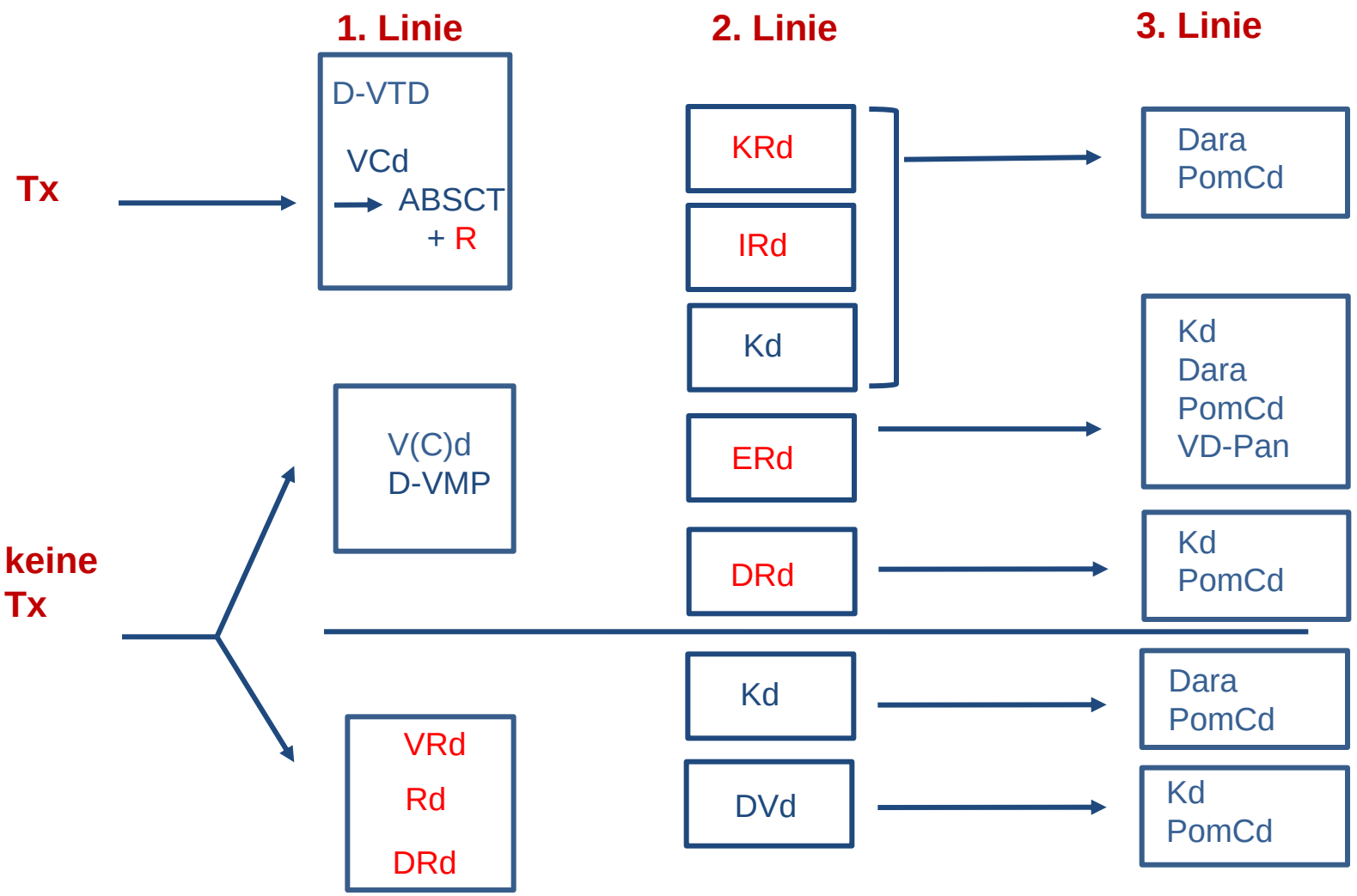
    - Bispezifische Ak

Therapiesequenzen
R-haltige Regime

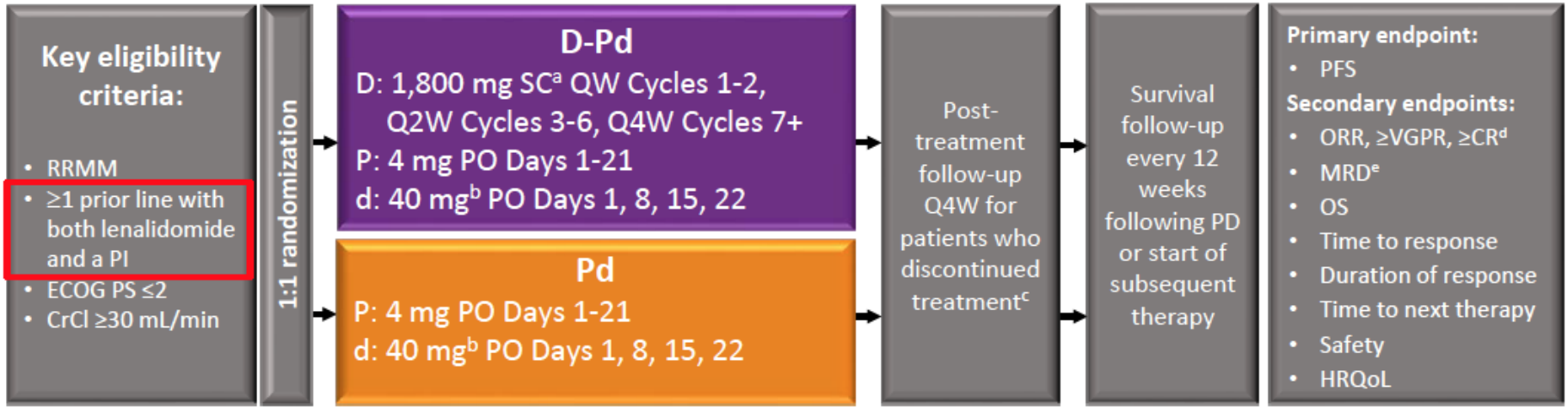


Len-Refraktärität

- **Pomalidomid-basierte Kombinationen**
  - **Elotuzumab:** ELOQUENT-3
  - **Bortezomib:** OPTIMISMM
  - **Isatuximab:** ICARIA-MM
  - **Daratumumab:** APOLLO
- **Carfilzomib-basierte Kombinationen**
  - **Daratumumab:** CANDOR
  - **Isatuximab:** IKEMA

ASH 2020

APOLLO: Dara-Pomd vs. Pomd



Dimopoulos et al. ASH 2020. Abstract #412

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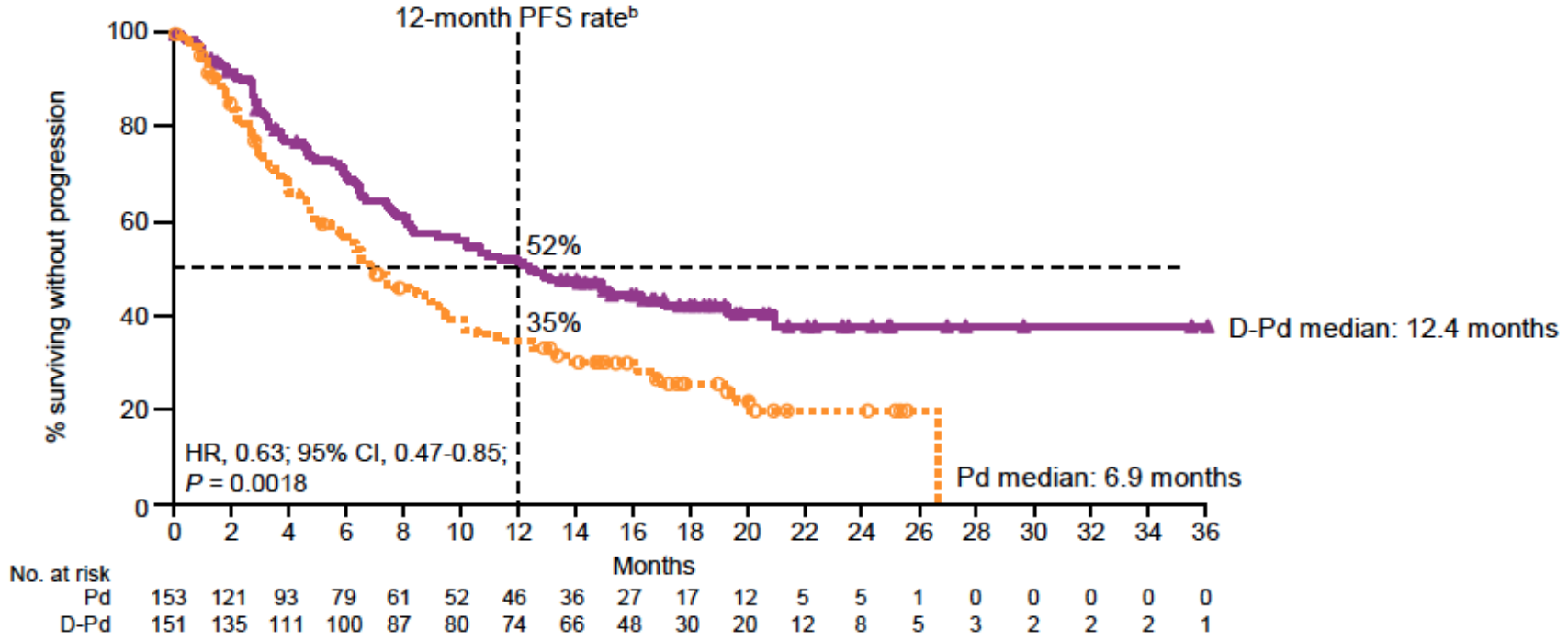
APOLLO: Dara-Pomd vs. Pomd

Follow up: 16,9 Monate

PFS



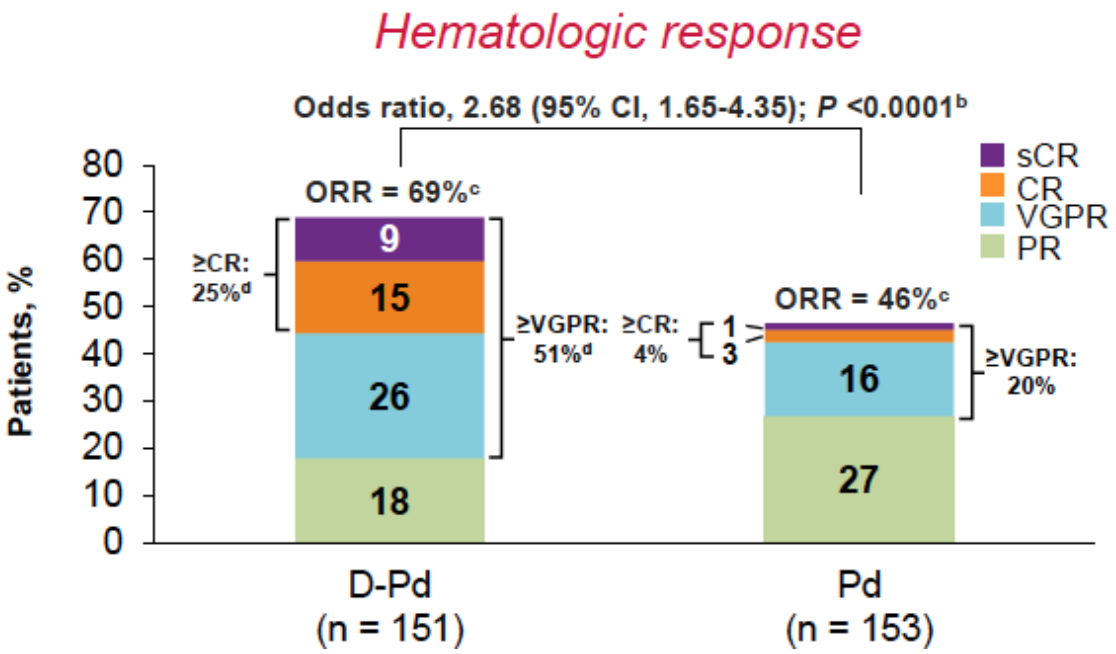
- Median PFS among patients refractory to lenalidomide was 9.9 months for D-Pd and 6.5 months for Pd

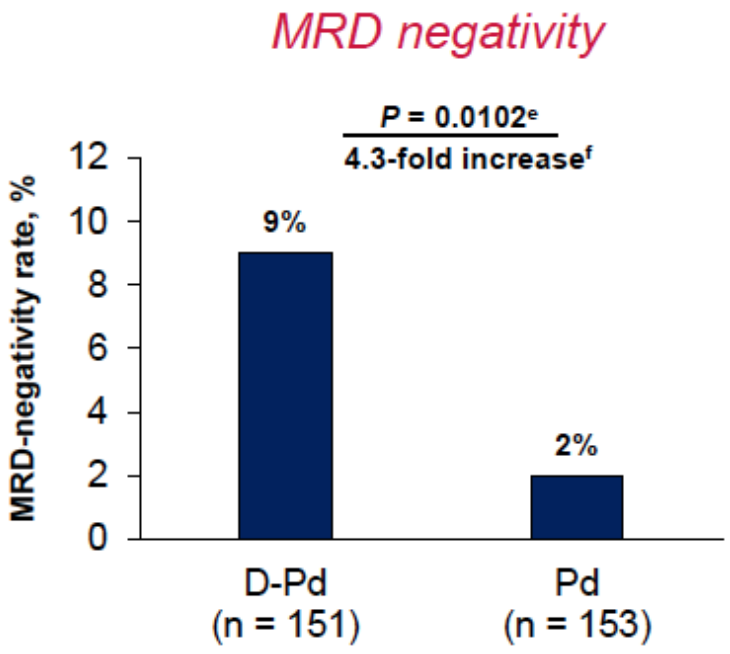
Dimopoulos et al. ASH 2020. Abstract #412

ASH 2020

APOLLO: Dara-Pomd vs. Pomd

ORR

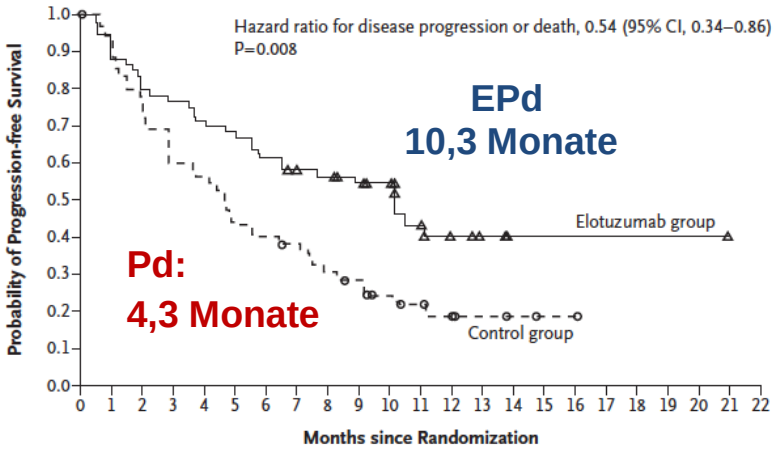




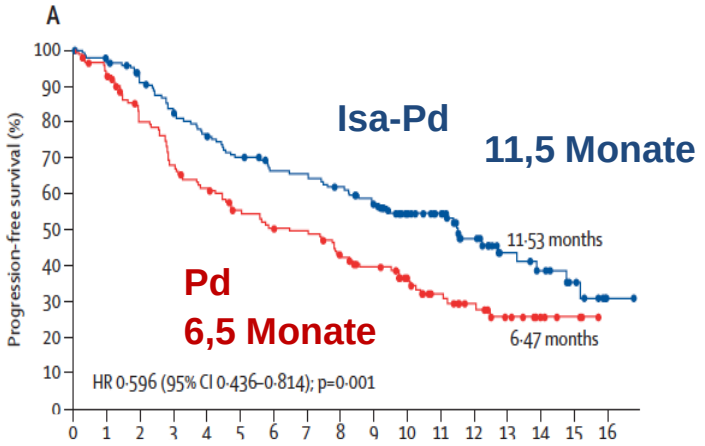
Dimopoulos et al. ASH 2020. Abstract #412

Len-Refraktärität: PFS

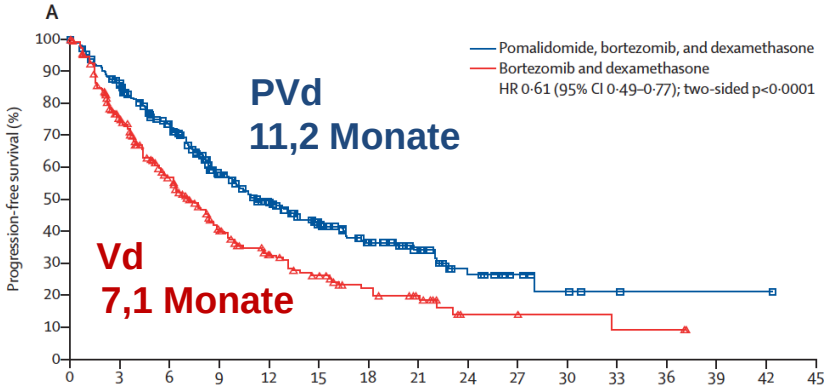
EPd: Elotuzumab – Pomalidomid – Dexamethason



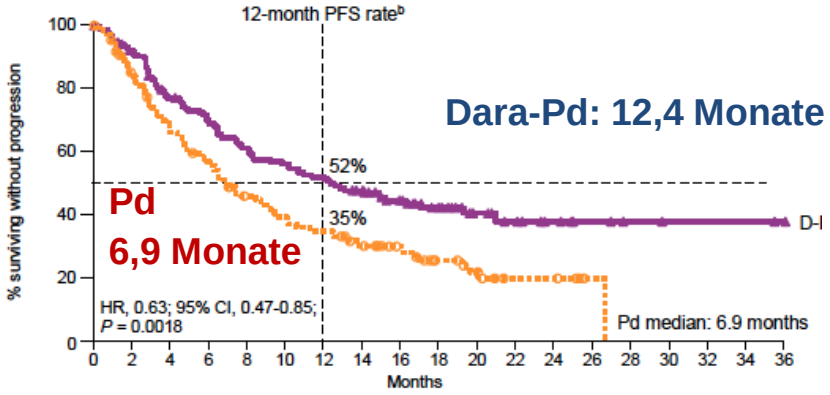
IsaPd: Isatuximab – Pomalidomid – Dexamethason



PVd: Pomalidomid – Bortezomib – Dexamethason



Dara-Pd: Daratumumab – Pomalidomid – Dexamethason



Len-Refraktärität

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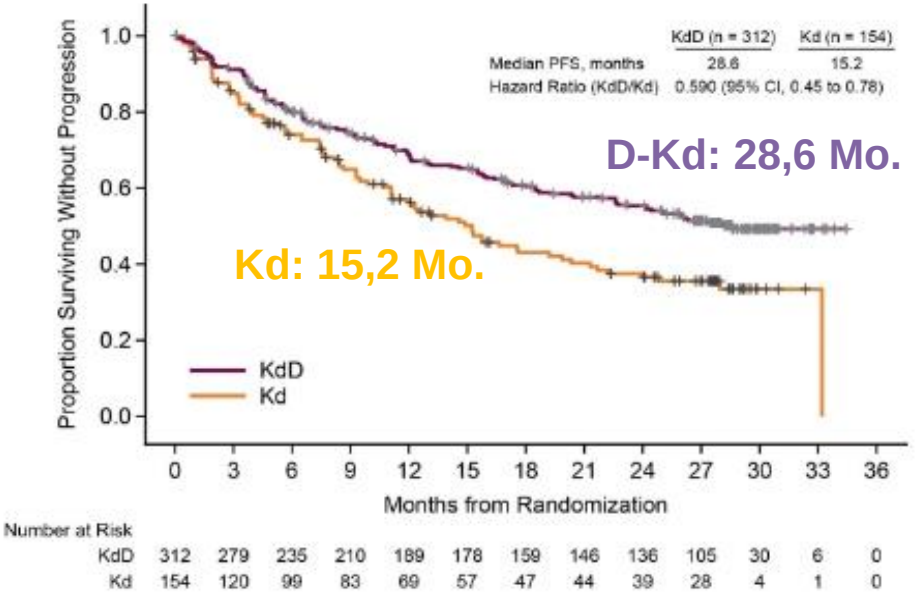
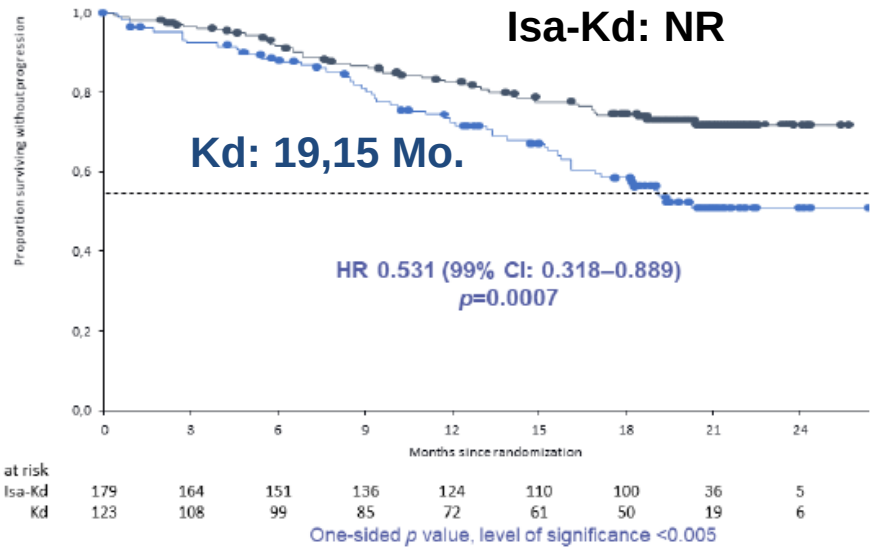
  - **Daratumumab:** CANDOR
  - **Isatuximab:** IKEMA

Len-Refraktärität: PFS

CANDOR: D-Kd vs. Kd



IKEMA: ISA-Kd vs. Kd



ASH 2020

Dimopoulos M, et al. ASH 2020. Abstract 2325

Moreau P et al. LBA 2603; EHA 2020

Behandlungssequenzen

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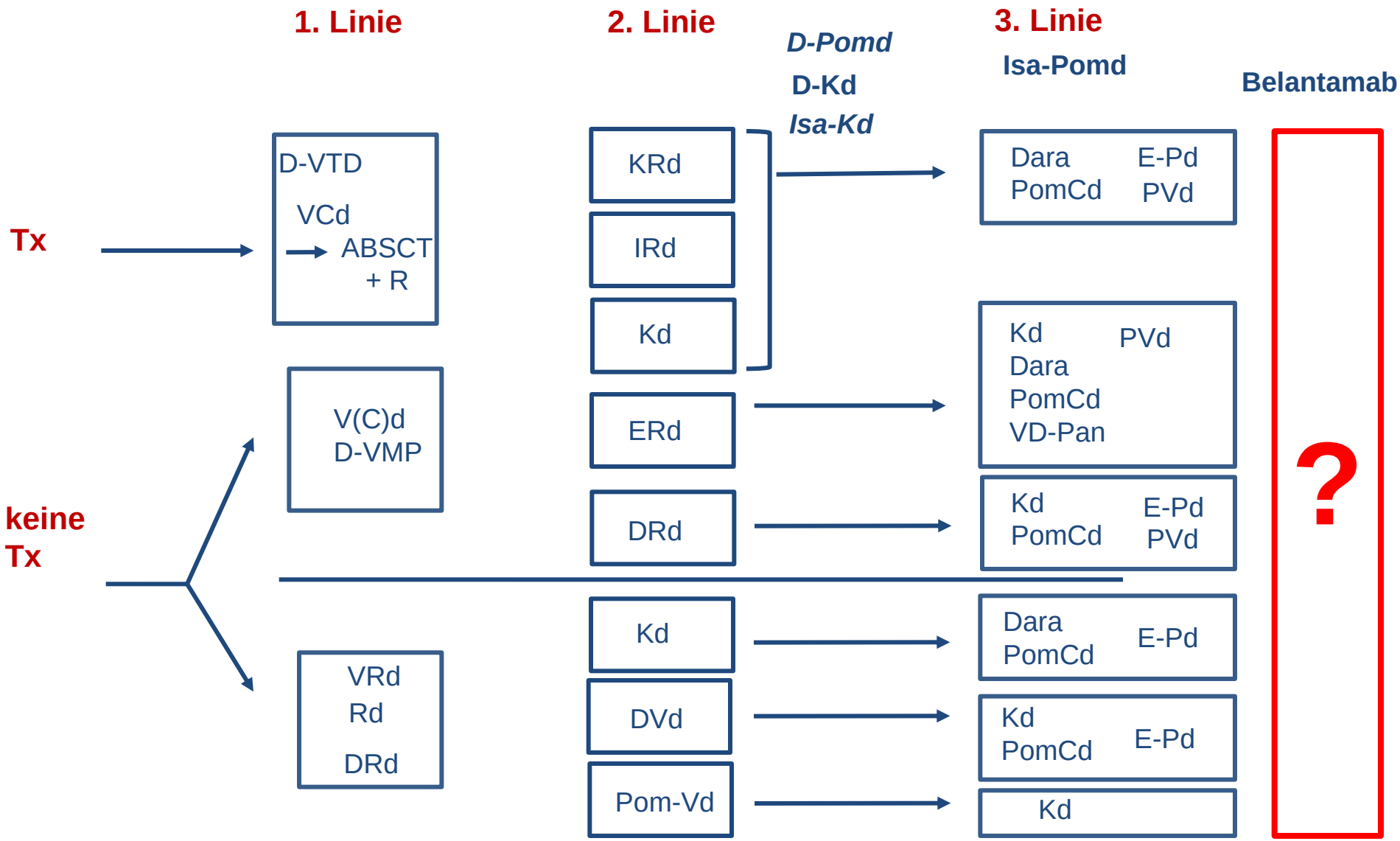

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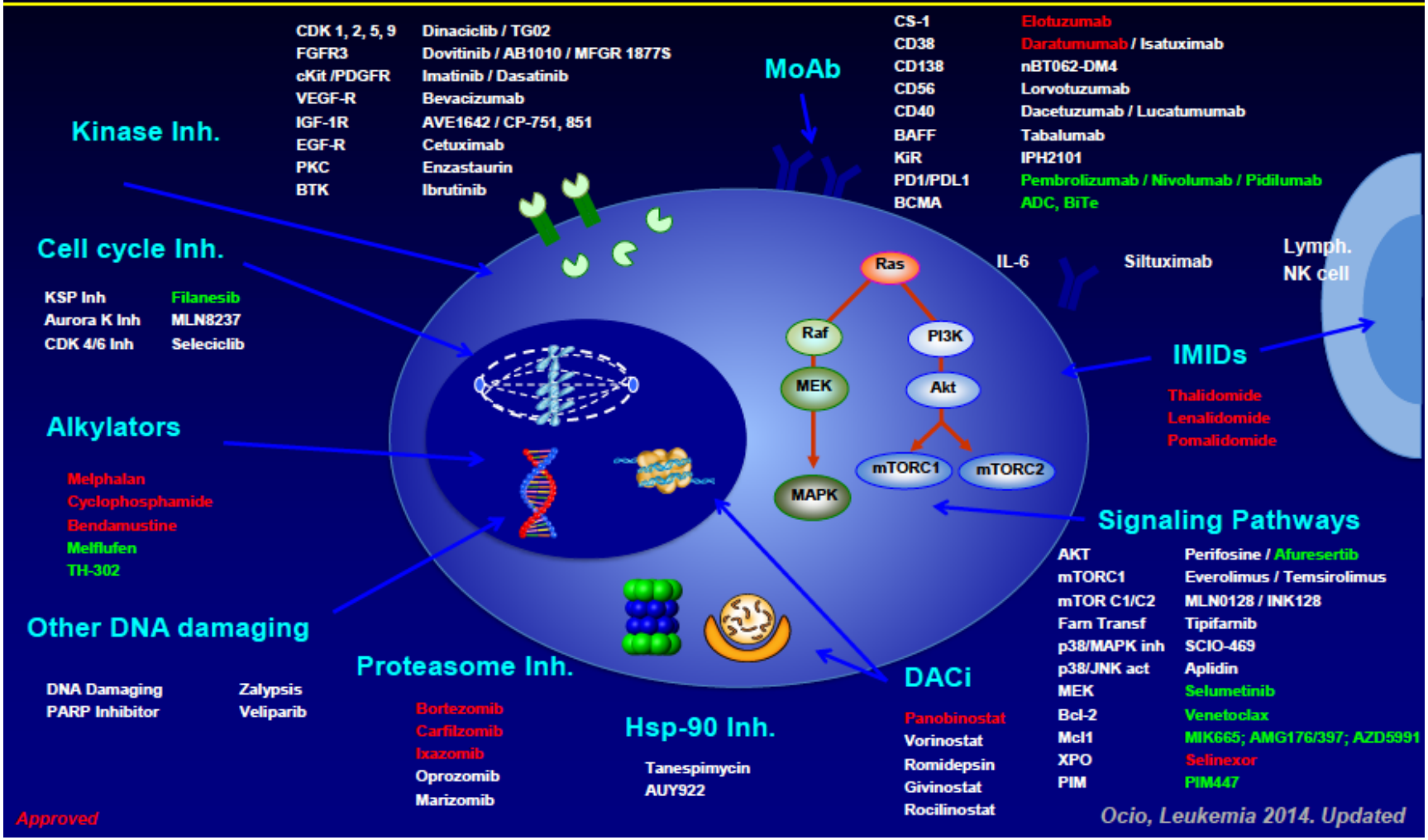
New drugs and mechanisms of action in MM



BIRMA Studie

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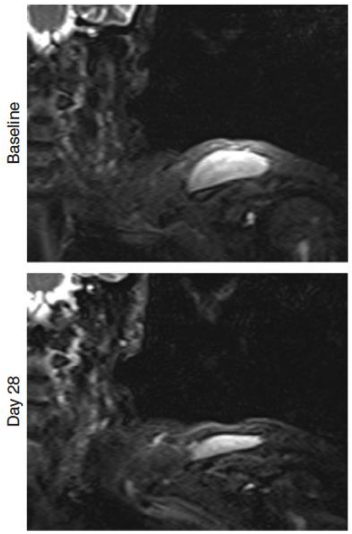
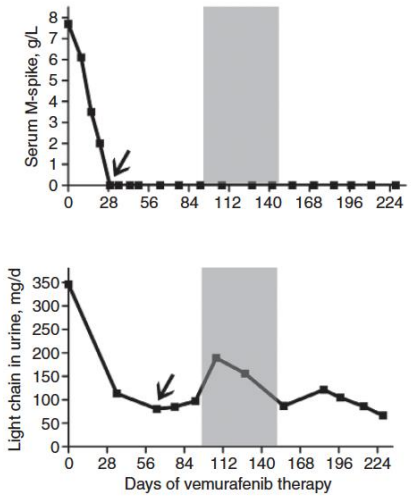
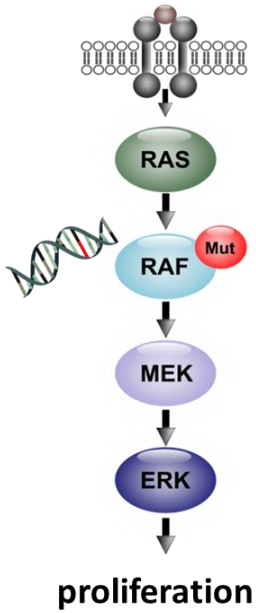




Andrulis M et al. *Cancer Discovery* 2013

BRAF V600E/K Mutation



Drug Combination :

- encorafenib
- binimetinib

ASH 2020

Response:

ORR	82%
>= PR:	9/11
>= VGPR:	6/11
CR/nCR:	3/11

(Raab et al. Abstract 294 / ASH 2020)

rrMM:
Braf Mutation testen !

BELLINI Studie

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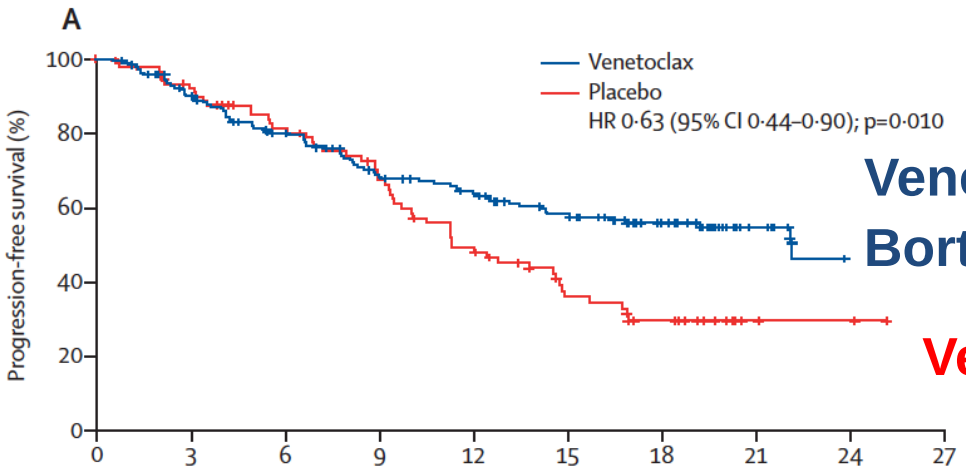
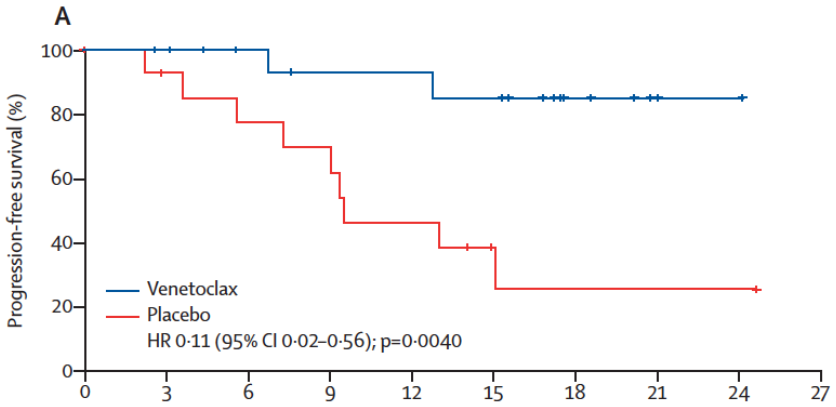
PFS



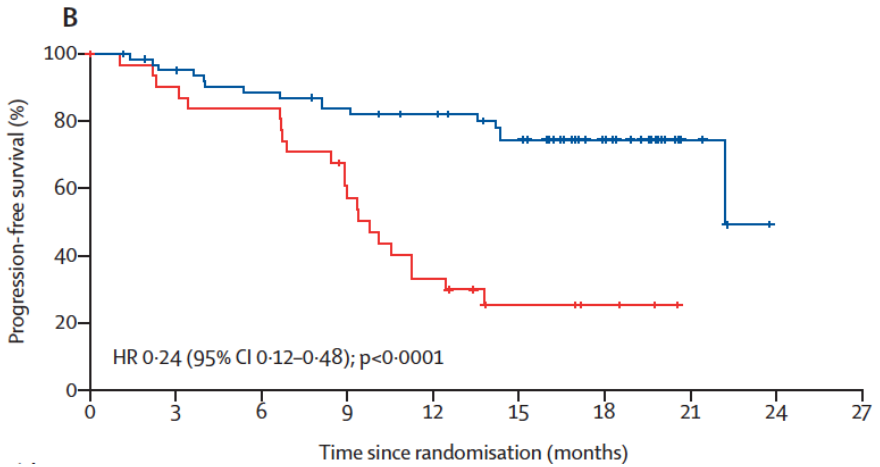
Venetoclax-Bortezomib-dex: 22,4 Mo.

Venetoclax-dex: 11,5 Mo.

t(11;14)



Bcl-2^{high}



Kumar S et al. 2020 *Lancet Oncol*. 12:1630-1642

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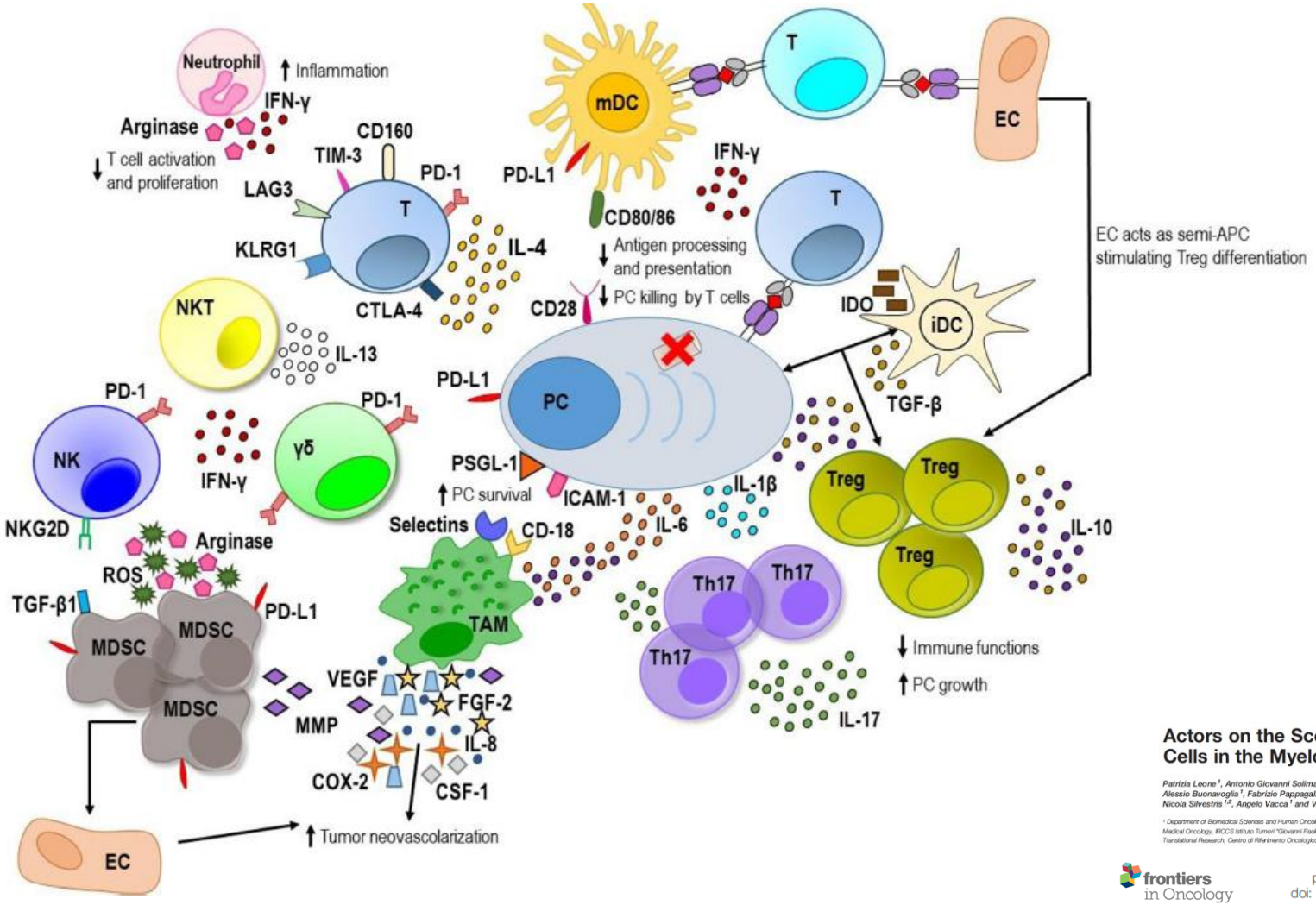
    - **Bispezifische Ak**

Immunzellen – MM Interaktionen



Actors on the Scene: Immune Cells in the Myeloma Niche

Patrizia Leone[1], Antonio Giovanni Solimando[1,2], Eleonora Malerba[1], Rossella Fasano[1], Alessio Buonavoglia[1], Fabrizio Pappagallo[1], Valli De Re[3], Antonella Argentiero[3], Nicola Silvestris[1,2], Angelo Vacca[1] and Vito Racanelli[1]*

[1] Department of Biomedical Sciences and Human Oncology, University of Bari Medical School, Bari, Italy, [2] Department of Medical Oncology, IRCCS Istituto Tumori "Giovanni Paolo II" of Bari, Bari, Italy, [3] Bio-Proteomics Facility, Department of Translational Research, Centro di Riferimento Oncologico di Aviano (CRO) IRCCS, Aviano, Italy

frontiers in Oncology
REVIEW
published: 29 October 2020
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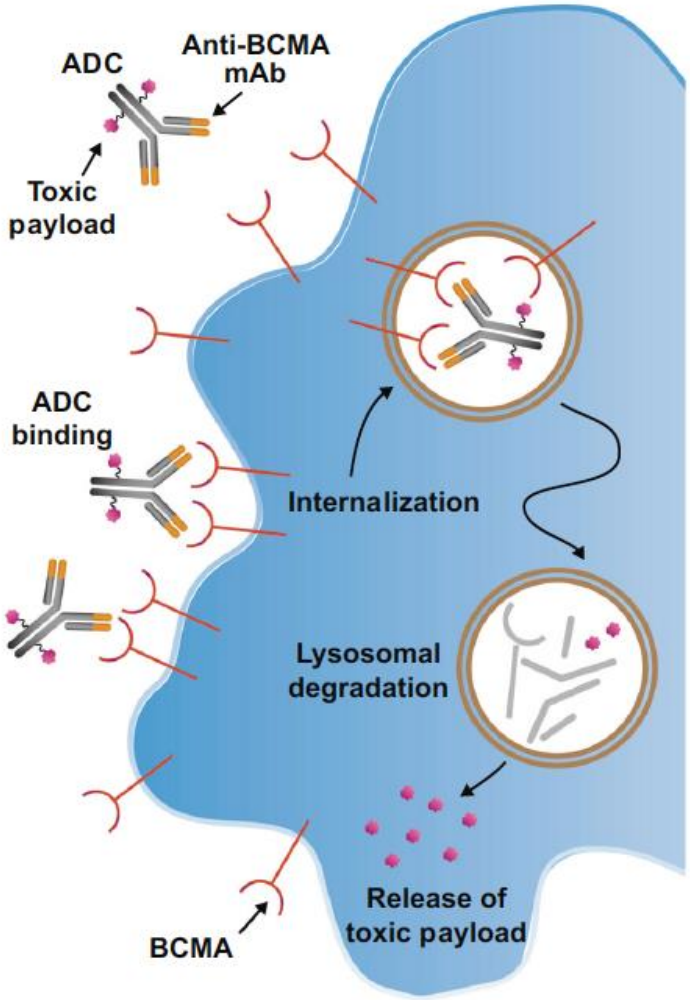
AGENDA

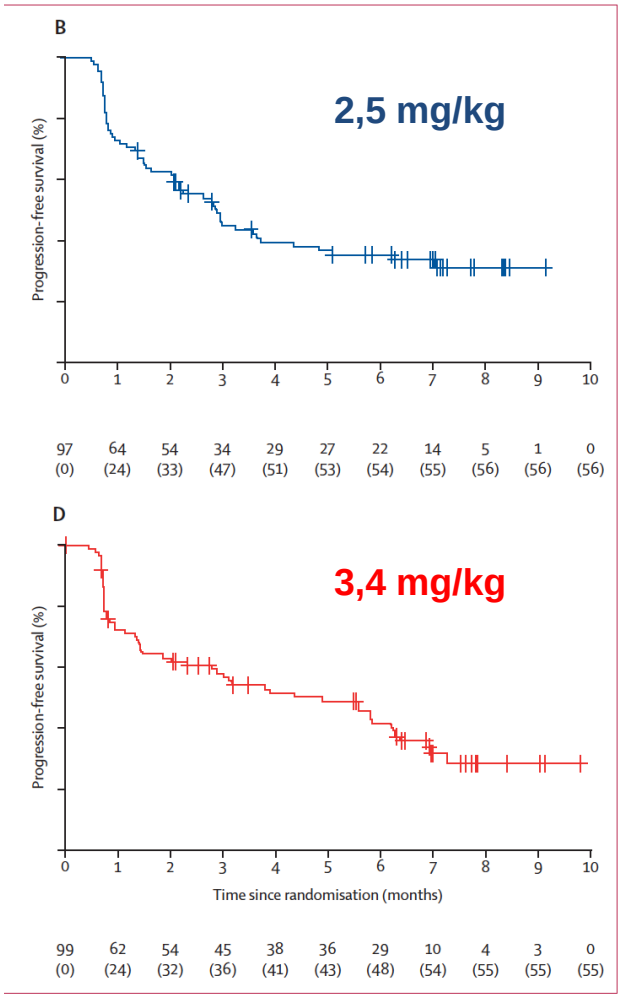
- Erstlinie
- **Rezidiv**
  - Lenalidomid – Refraktärität
  - Neue Substanzen
  - **Immuntherapie**
    - **Immunkonjugate**
    - CAR-T
    - Bispezifische Ak

Belantamab-Mafodotin



Shah et al. *Leukemia* 2020

DREAMM-2: Belantamab Mafodotin



AEs ≥Grade 3 occurring in ≥5% of patients in either group, n (%)*	Belantamab Mafodotin 2.5 mg/kg (N = 95)
Any event	80 (84)
Keratopathy (MECs)†	44 (46)
Anemia	20 (21)
Thrombocytopenia‡	21 (22)
Lymphocyte count decreased	12 (13)
Neutropenia§	10 (11)
Hypercalcemia	7 (7)
Pneumonia	6 (6)
GGT increased	3 (3)
Hypertension	4 (4)
AST increased	2 (2)
Fatigue	2 (2)

Lonial S et al. Lancet Oncol 2020:21: 207-221

AGENDA

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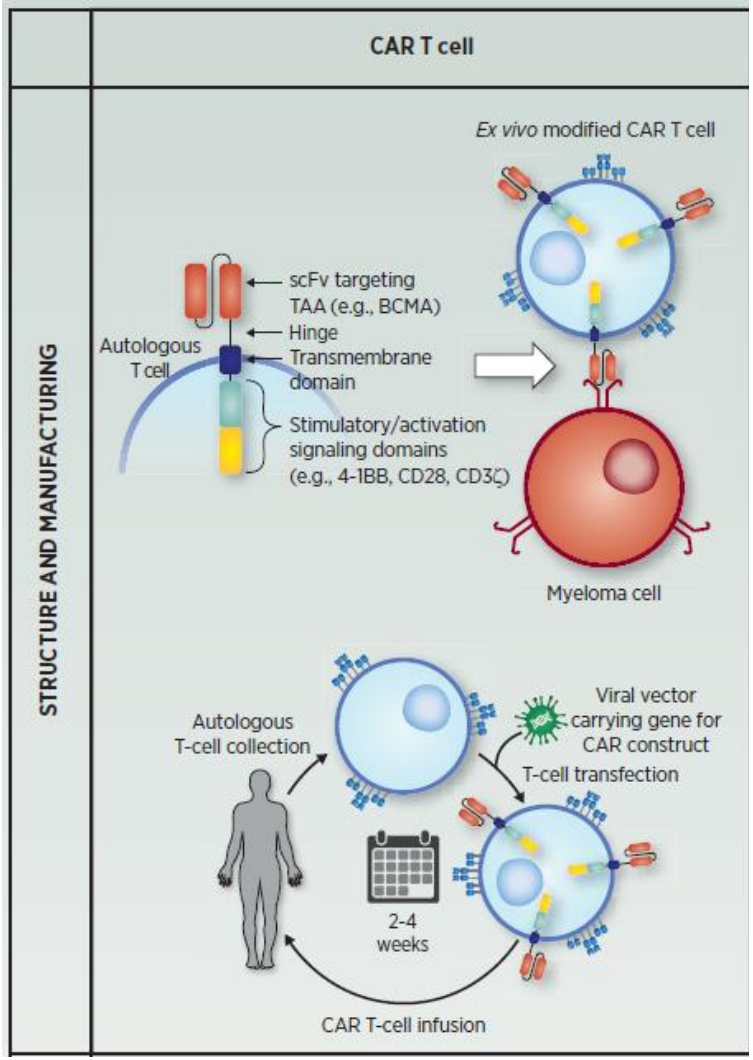
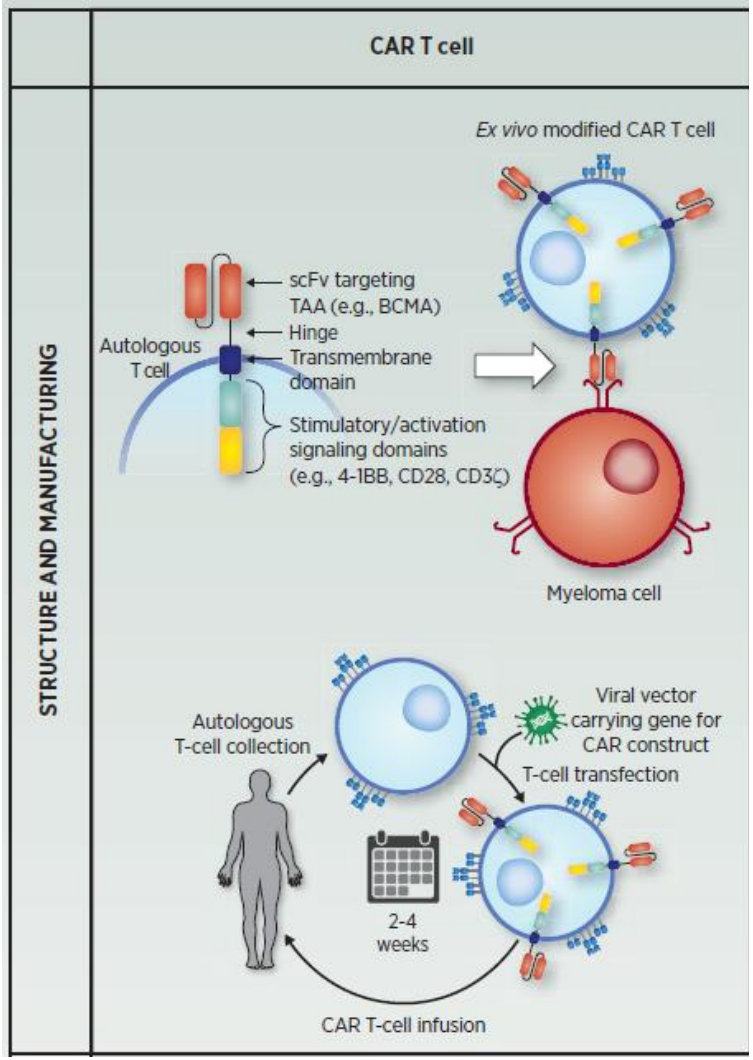
Zelluläre Immuntherapie



Cohen et al. *Clin Cancer Res* 2019

Ali SA et al. *Blood* 2016

Zelluläre Immuntherapie

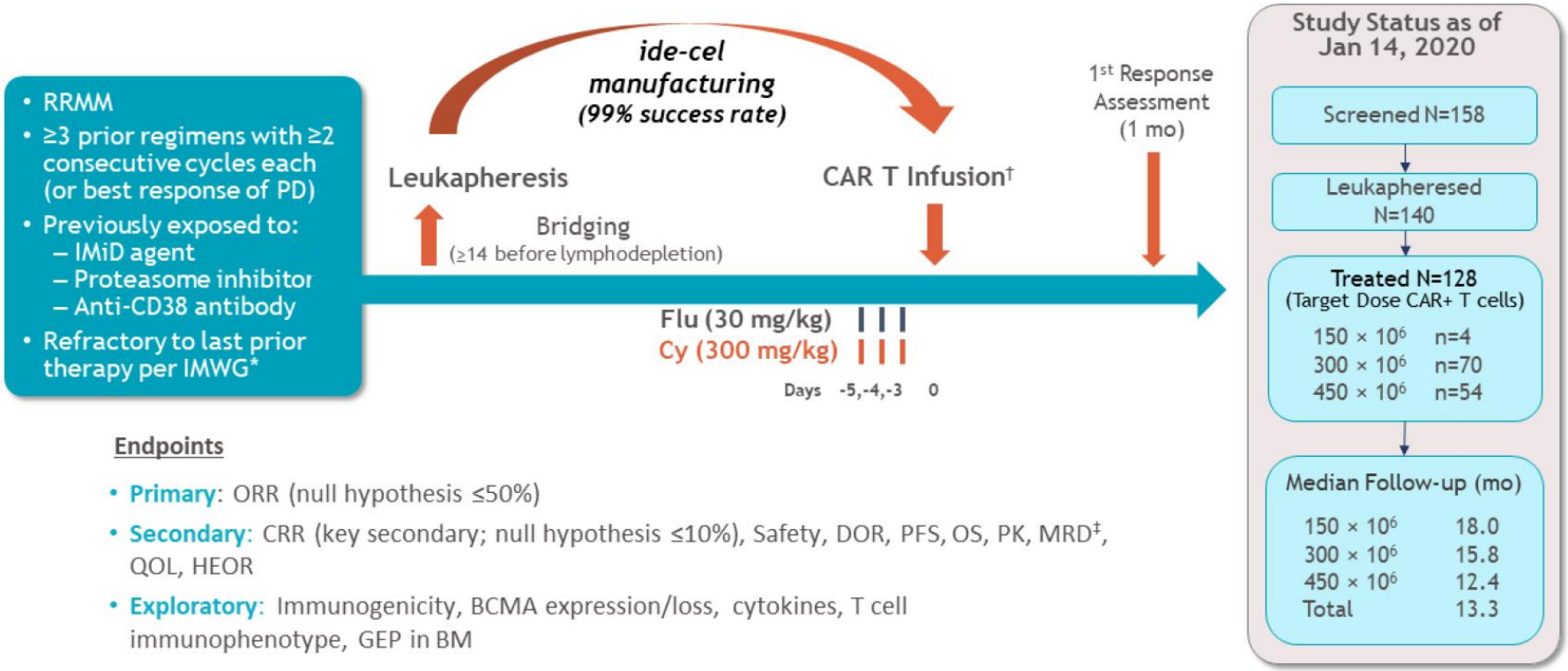


	α-CD19-BBz	α-Kappa-28z	α-CD138-28z	α-BCMA-28z	α-BCMA-BBz	α-BCMA-BBz
	α-CD19 scFV, 4-1BB, CD3ζ	α-Kappa scFV, CD28, CD3ζ	α-CD138 scFV, CD28, CD3ζ	α-BCMA scFV, CD28, CD3ζ	α-BCMA scFV, 4-1BB, CD3ζ	α-BCMA scFV, 4-1BB, CD3ζ
Institution	Penn	Baylor	Chinese PLA General Hospital	NCI	Penn	bluebird bio
scFV Clone	FMC63	CRL-1758	NK-92	11D5-3	ND	bb2121
scFV Origin	Murine	Murine	Murine	Murine	Human	Humanized
Gene Transfer System	Lentivirus	Retrovirus	Lentivirus	Retrovirus	Lentivirus	Lentivirus
Intracellular Domain	4-1BB ICD-CD3zeta	CD28 ICD-CD3zeta	CD28 ICD-CD3zeta	CD28 ICD-CD3zeta	4-1BB ICD-CD3zeta	4-1BB ICD-CD3zeta
Patients Treated	11	8	5	12	6	9
Dose(s)	1-5e7 CARTs/pt	0.2-2e8 CARTs/m2	0.44-1.51e7 CARTs/kg	0.3-9e6 CARTs/kg	1e7-5e8 CARTs/pt	5-80e7 CARTs/pt
Best Response (number of patients)	CR (1), VGRP (6), PR (2), PD (2)	SD (5), NR (3)	SD (4), PD (1)	Stringent CR (1), VGPR (2), PR (1), SD (8)	Stringent CR (1), VGPR (1), SD (1), MR (2), PD (1)	Stringent CR (2), VGPR (1), PR (4), SD (1), PD (1)
Reference(s)	25··	27··	26	28	29	ASH 2016 Abstract

Curr Hematol Malig Rep (2017) 12:119–125

Cohen et al. *Clin Cancer Res* 2019

KarMMa



Endpoints

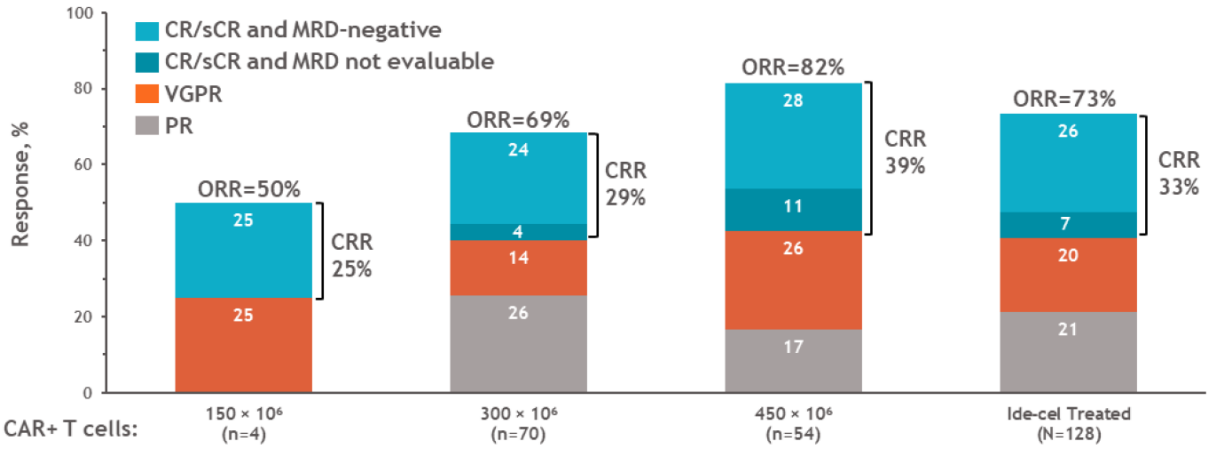
- **Primary**: ORR (null hypothesis ≤50%)
- **Secondary**: CRR (key secondary; null hypothesis ≤10%), Safety, DOR, PFS, OS, PK, MRD‡, QOL, HEOR
- **Exploratory**: Immunogenicity, BCMA expression/loss, cytokines, T cell immunophenotype, GEP in BM

San Miguel et al. *EHA 2020. #S209*

KarMMa

Characteristics		Ide-cel Treated (N=128)
Time since initial diagnosis, median (range), y		6 (1–18)
No. of prior anti-myeloma regimens, median (range)		6 (3–16)
Prior autologous SCT, %	1	94
	>1	34
Any bridging therapies for MM, %		88
Refractory status, %	IMiD agent-refractory	98
	PI-refractory	91
	Anti-CD38 Ab-refractory	94
	Triple-refractory	84
	Penta-refractory	26

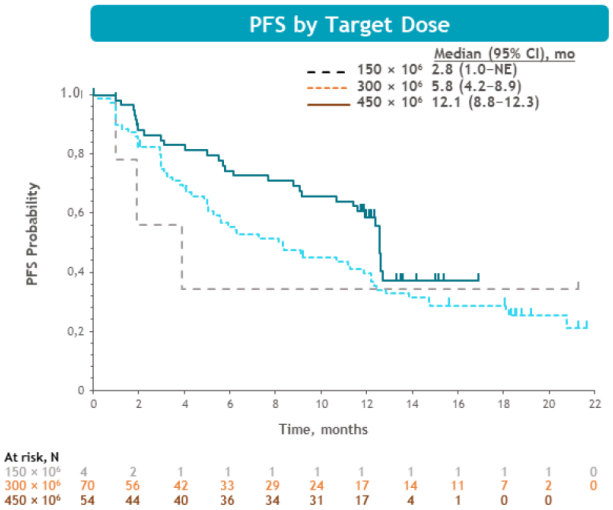
ORR

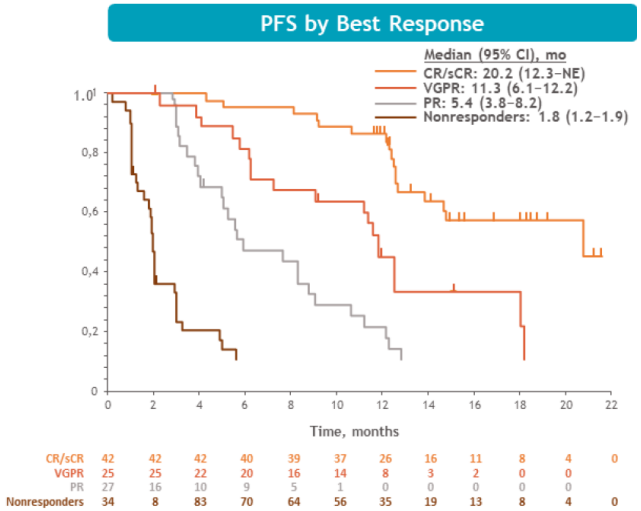


San Miguel et al. *EHA 2020. #S209*

KarMMa

PFS





III. Med. Klinik
Q2 / 2021

Sicherheit

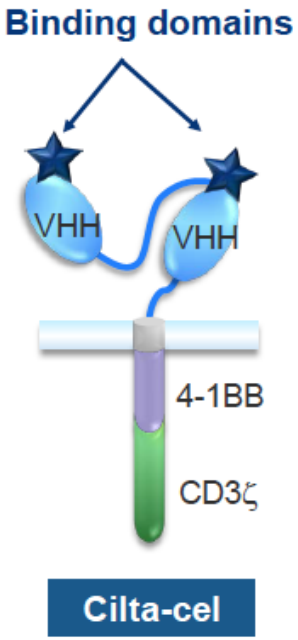
AE,* n (%)	Ide-cel Treated (N=128)	
	Any Grade	Grade ≥3
Hematologic		
Neutropenia	117 (91)	114 (89)
Anemia	89 (70)	77 (60)
Thrombocytopenia	81 (63)	67 (52)
Leukopenia	54 (42)	50 (39)
Lymphopenia	35 (27)	34 (27)
Gastrointestinal		
Diarrhea	45 (35)	2 (2)
Nausea	37 (29)	0
Other		
Hypokalemia	45 (35)	3 (2)
Fatigue	43 (34)	2 (2)
Hypophosphatemia	38 (30)	20 (16)
Hypocalcemia	34 (27)	10 (8)
Pyrexia	32 (25)	3 (2)
Hypomagnesemia	30 (23)	0
Decreased appetite	27 (21)	1 (<1)
Headache	27 (21)	1 (<1)
Hypogammaglobulinemia	27 (21)	1 (<1)
Cough	26 (20)	0
CRS†	107 (84)	7 (5)

San Miguel et al. *EHA 2020. #S209*

ASH 2020

CARTITUDE-1

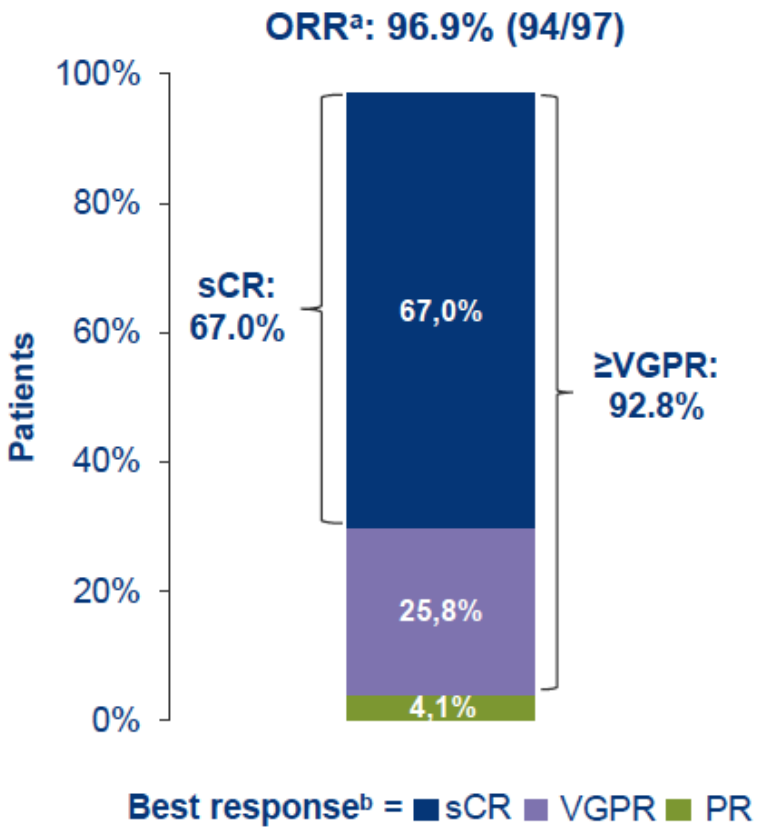
- Ciltacabtagene autoleucel (cilta-cel; JNJ-68284528) is a chimeric antigen receptor T-cell therapy
  - 2 BCMA-targeting single-domain antibodies designed to confer avidity
- In the phase 1b portion of the CARTITUDE-1 study, cilta-cel yielded deep, durable responses with a manageable safety profile in patients with relapsed/refractory MM[1]
- Here, we report initial results from the combined phase 1b/2 CARTITUDE-1 study of cilta-cel

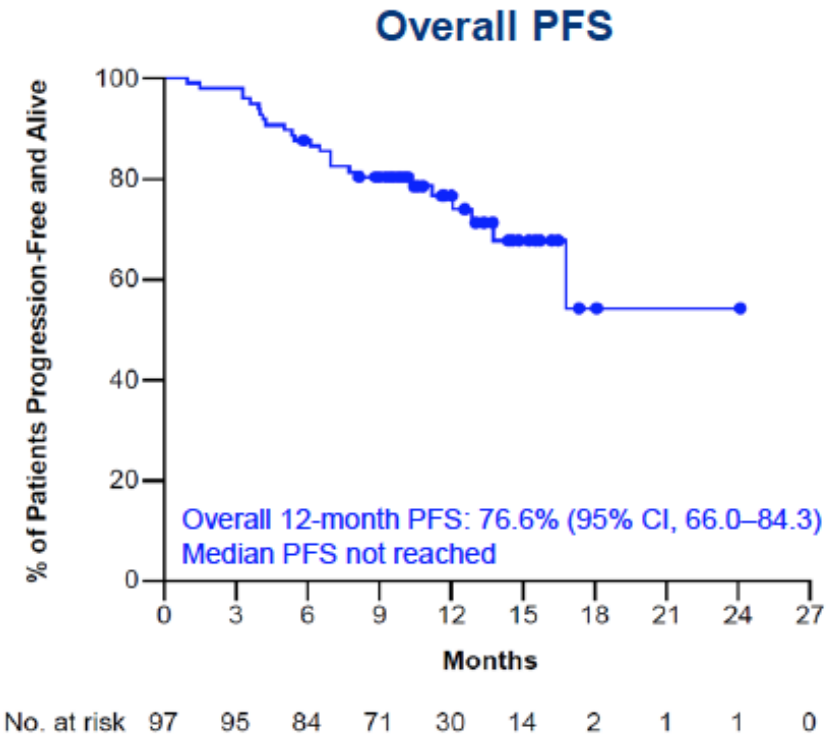


Madduri et al. *ASH 2020. #177*

ASH 2020

CARTITUDE-1





Madduri et al. *ASH 2020. #177*

BCMA CART

Table 1. Selected landmark clinical trials of BCMA-targeted CAR T cells in RRMM (with n > 10)

Study	n	Phase	Vector	Product	Costimulatory domain	LD chemotherapy	CAR T-cell dose	Lines of prior treatment, median (range), n	Triple class refractory, %	Previous ASCT, %	CRS any grade, %	CRS grade ≥3, %	ICANS grade ≥3, %	Anti–IL-6 therapy, %	ORR, %	≥VGPR, %	CR, %	MRD negative, %*	PFS, median	OS, median
CRB-401[3]	33	1	Lenti	Ide-cel (bb2121)	4-1BB	Flu/Cyc	50/150/450/800 × 10^6 cells	7 (3-23)	N/A	97	76	6	3	21	85	72	45	94 (15/16; ≥PR patients)	11.8 mo	N/A
KarMMA[4]	128	2	Lenti	Ide-cel (bb2121)	4-1BB	Flu/Cyc	150/300/450 × 10^6 cells	6 (3-16)	84	94	84	6	3	2	73	53	33	33 (26/128; CR patients)	8.8 mo	19.4 mo
LEGEND-2[9]	57/74	1	Lenti	LCAR-B38M (JNJ68284528)	4-1BB	Cyc	0.5 × 10^6 (0.07-2.1) cells/kg	3 (1-9)	N/A	18	90	7	0	46	89	78	74	68.4 (39/57; CR patients)	19.9 mo	36.1 mo
CARTITUDE-1[7,50]	29	1b/2	Lenti	LCAR-B38M (JNJ68284528)	4-1BB	Flu/Cyc	0.75 × 10^6 (0.5-1.0) cells/kg	5 (3-18)	86	86	93	7	3	76	100	97	86	81 (13/16; CR patients)	87% (9 mo)	N/A
EVOLVE[5]	44	1	Lenti	Orvacabtagene autoleucel (JCARH125)	4-1BB	Flu/Cyc	50/150/450 × 10^6 cells	7 (3-23)	N/A	68	80	9	7	34	82	48	27	67 (6/9) at day 29 (≥PR patients)	N/A	N/A
EVOLVE[47]	62	1	Lenti	Orvacabtagene autoleucel (JCARH125)	4-1BB	Flu/Cyc	300/450/600 × 10^6 cells	6 (3-18)	94	94	89	3	3	76	92	68	35	96 (21/25) at 3 mo (≥PR patients)	N/A	N/A
NCI[15]	16	1	Retro	N/A	CD28	Flu/Cyc	9 × 10^6 cells/kg	9.5 (3-19)	N/A	N/A	94	38	19	31	81	63	13	100 (≥PR patients)	31 wk	N/A
UPENN[16]	25	1	Lenti	N/A	4-1BB	None or Cyc	10/50/100/500 × 10^6 cells	7 (3-13)	44	92	88	32	12	28	63	28	8	33 (≥PR patients)	65-125 d	502 d
P-BCMA-101[45]	23	1/2	PiggyBac transposon	P-BCMA-101	4-1BB	Flu/Cy	51/152/456/845/1143 × 10^6 cells	6 (3-11)	N/A	83	10 (2/21)	0	5 (1/21)	5 (1/21)	63 (12/19)	26 (5/19)	N/A	N/A	N/A	N/A
FHCRC[6]	11	1	Lenti	FCARH143	4-1BB	Yes (not specified)	50/150 × 10^6 cells	11 (8-20)	91	82	18	0	0	18	100	82	36	N/A	N/A	N/A
CT053[51]	24	1	Retro	CT053	4-1BB	Flu/Cyc	150 × 10^6 cells	4.5 (2-11)	N/A	42	63	0	4	53 (8/15)	88	83	79	85 (17/20)	N/A	N/A
CT103A[52]	18	1	Lenti	CT103A	4-1BB	Flu/Cyc	1/3/6/8 × 10^6 cells/kg	4 (3-6)	N/A	39	94	22	0	N/A	100 (17/17)	88 (15/17)	71 (12/17)	100 at 10^{-4} (≥PR patients)	N/A	N/A

Wudhikarn et al. *Hematology Am Soc Hematol Educ Program*. 2020:272-279

CART und Myelom

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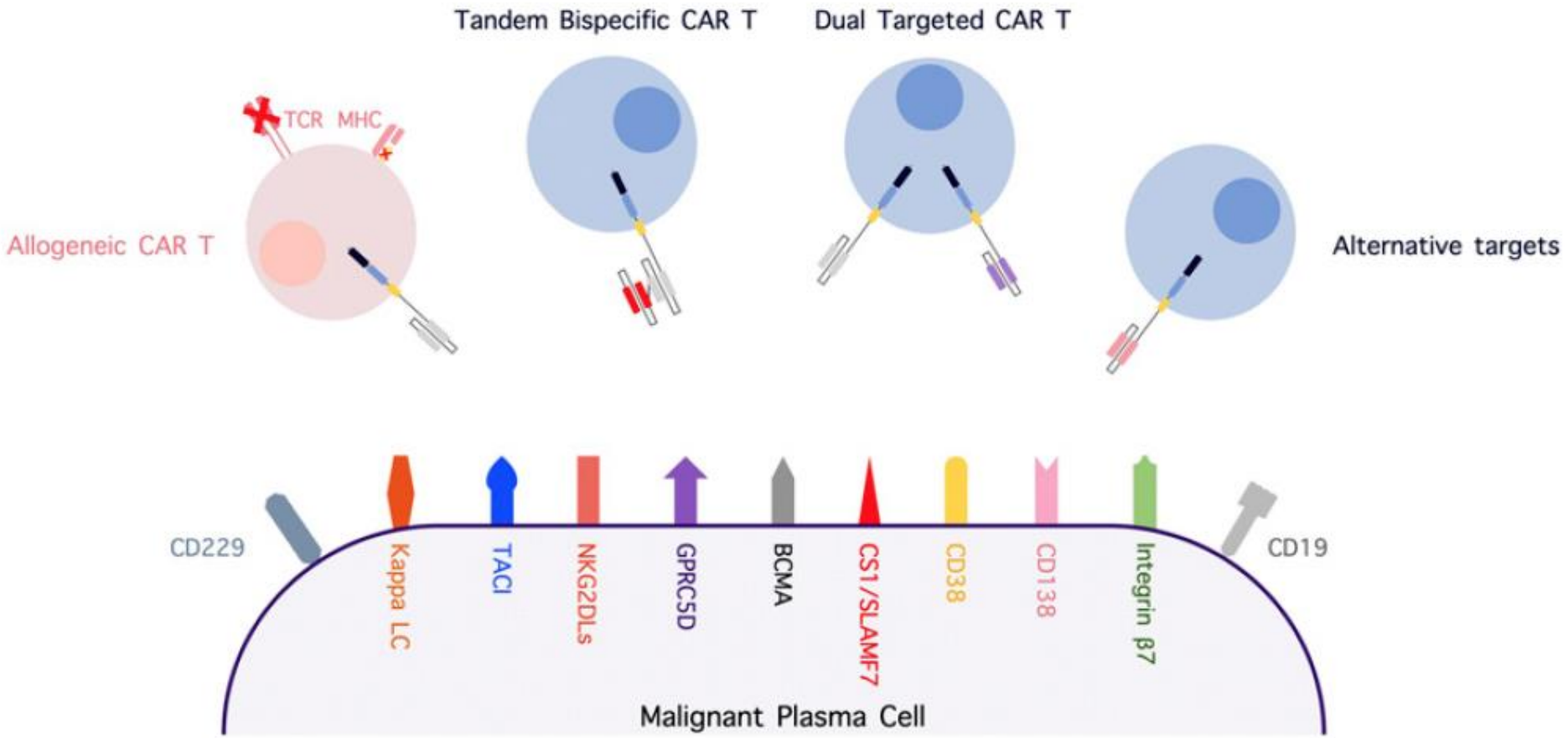
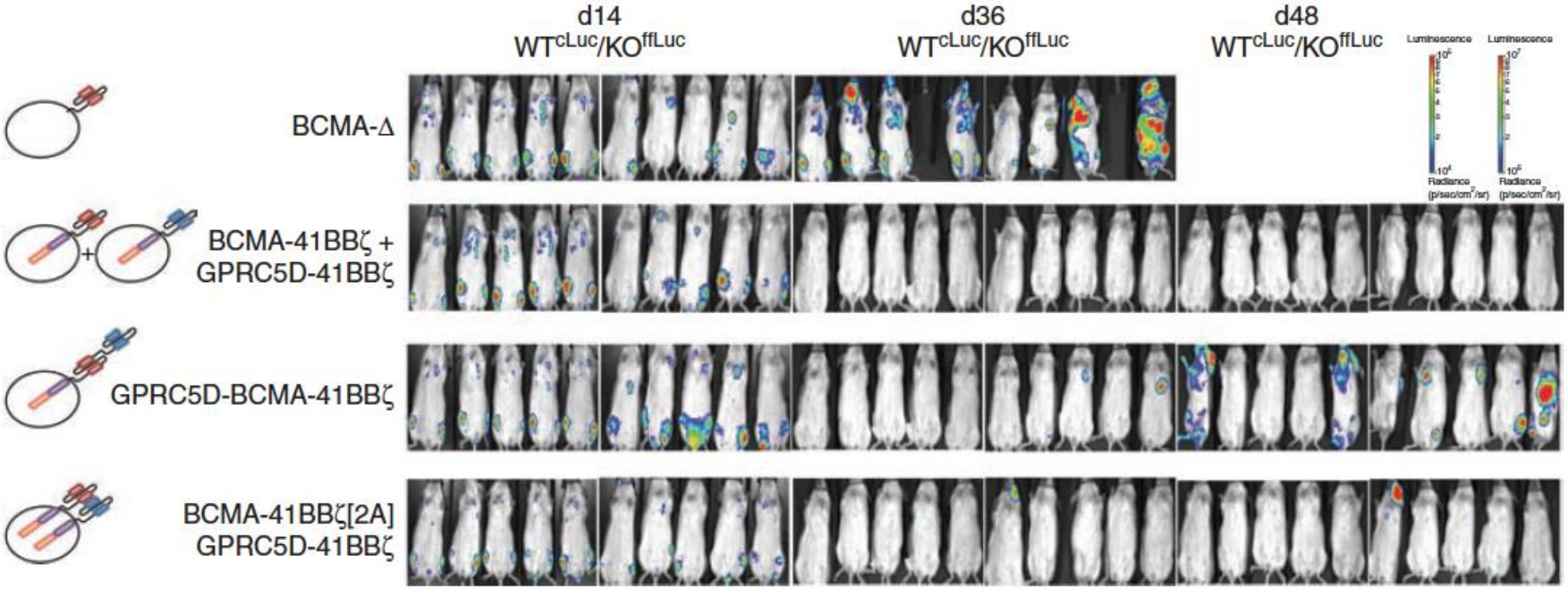
III. Medizinische Klinik und Poliklinik



Wudhikarn et al. *Hematology Am Soc Hematol Educ Program*. 2020:272-279

Dualer CAR-T



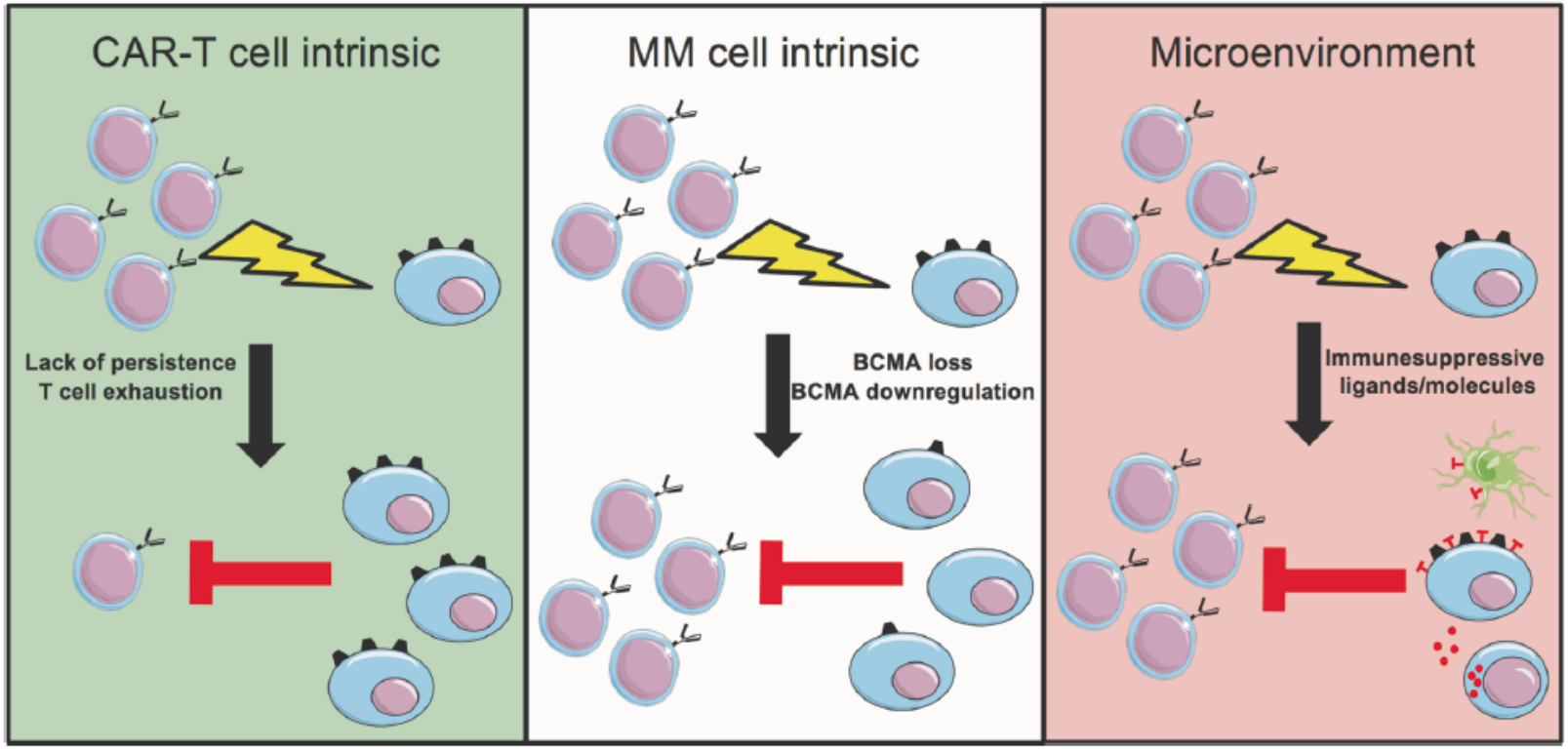
Defining an Optimal Dual-Targeted CAR T-cell Therapy Approach Simultaneously Targeting BCMA and GPRC5D to Prevent BCMA Escape–Driven Relapse in Multiple Myeloma

Carlos Fernandez de Larrea[1], Mette Staehr[1], Andrea V. Lopez[1], Khong Y. Ng[2], Yunxin Chen[1], William D. Godfrey[1], Terence J. Purdon[1], Vladimir Ponomarev[3], Hans-Guido Wendel[2], Renier J. Brentjens[1,4], and Eric L. Smith[1,5]

Blood Cancer Discov 2020;1:146–54
doi: 10.1158/2643-3230.BCD-20-0020

MM CART

CART Resistance



D'Agostino and Raje *Leukemia* 2020

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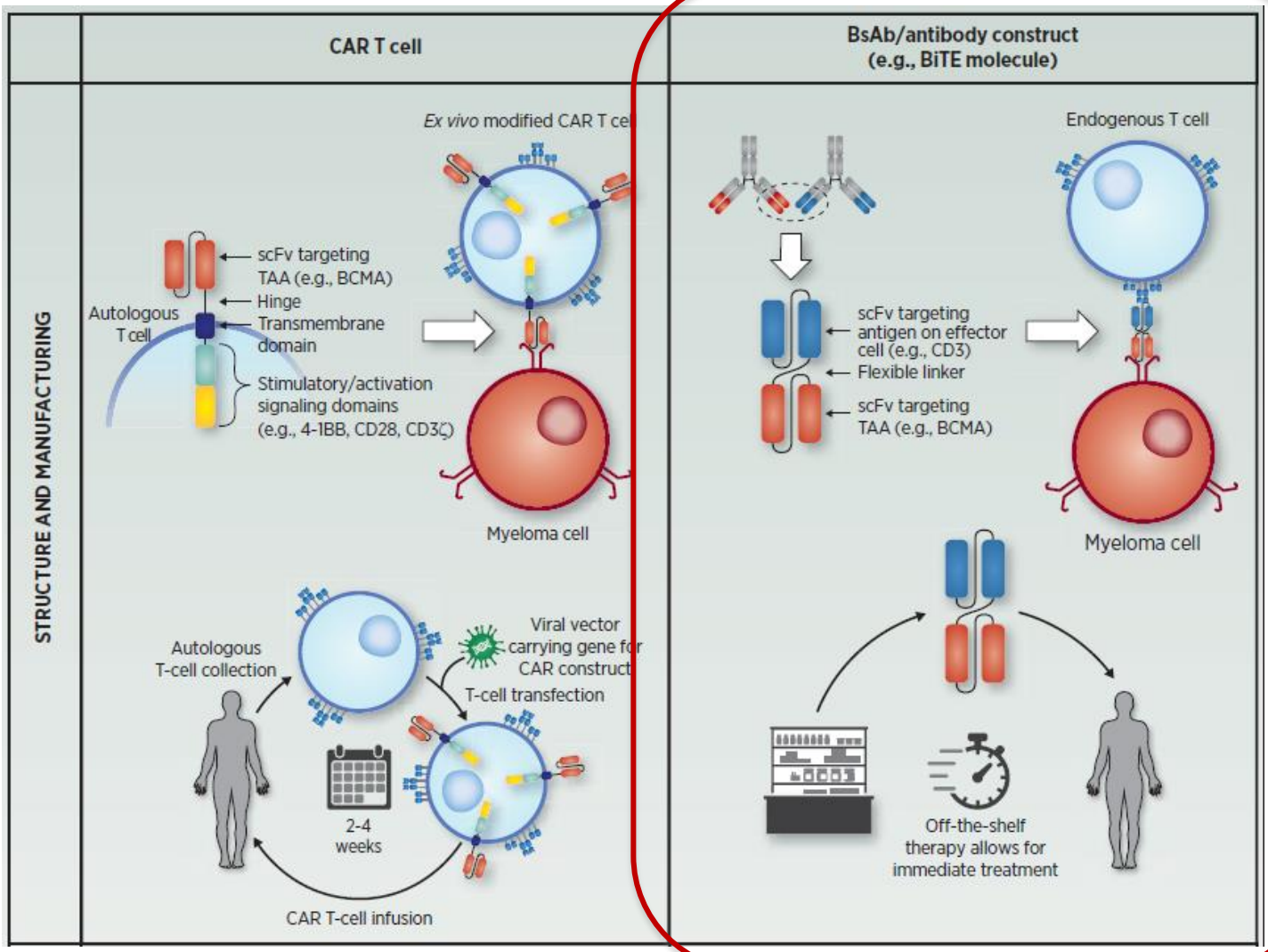
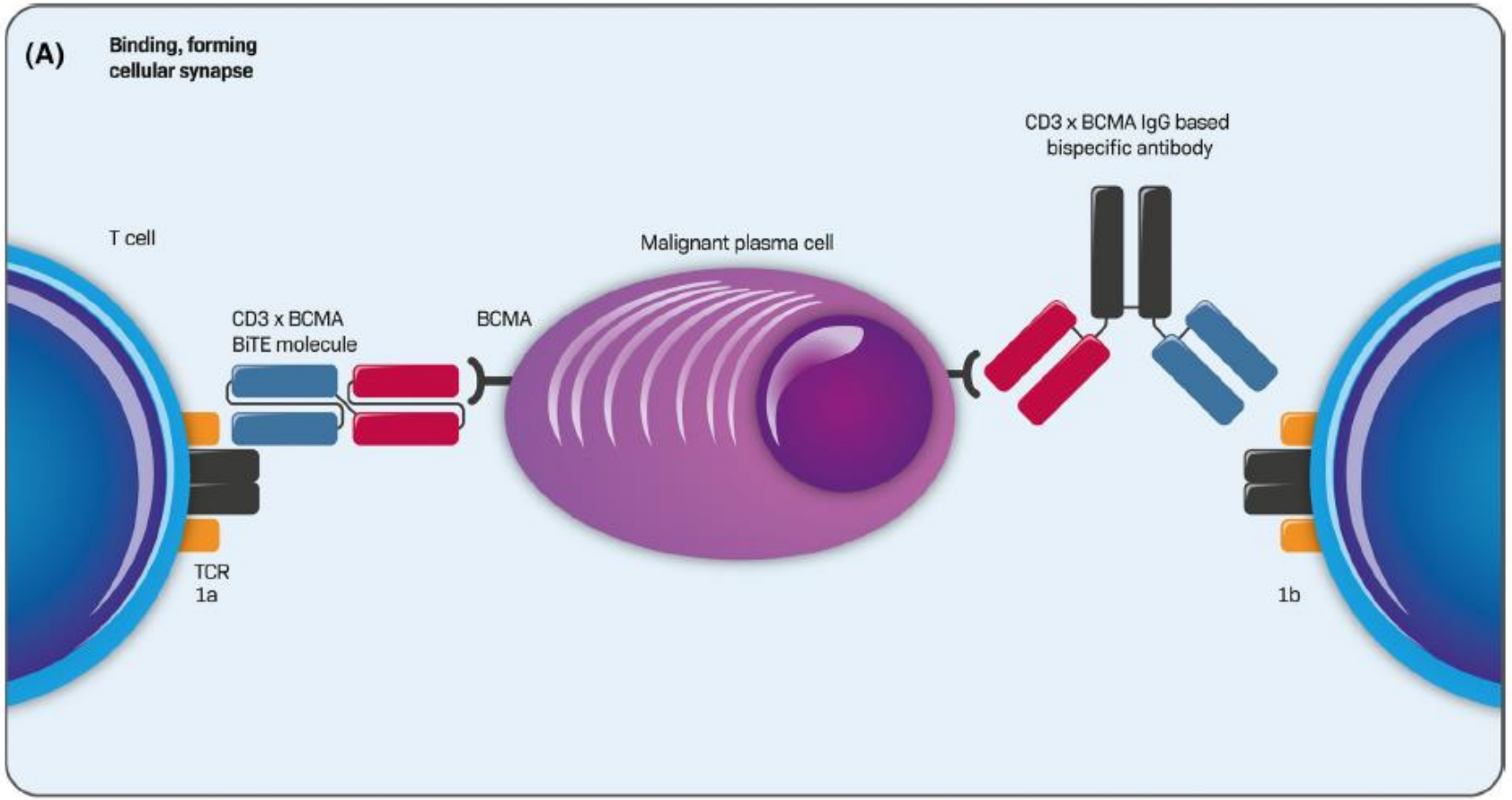
    - **Bispezifische Ak**

CART – BsAb – BiTE



Cohen et al. *Clin Cancer Res* 2019

Ab Konstrukte / MM



Demel I. et al. 2020 *Br J Haematol* doi: 10.1111/bjh.17235. Online ahead of print.

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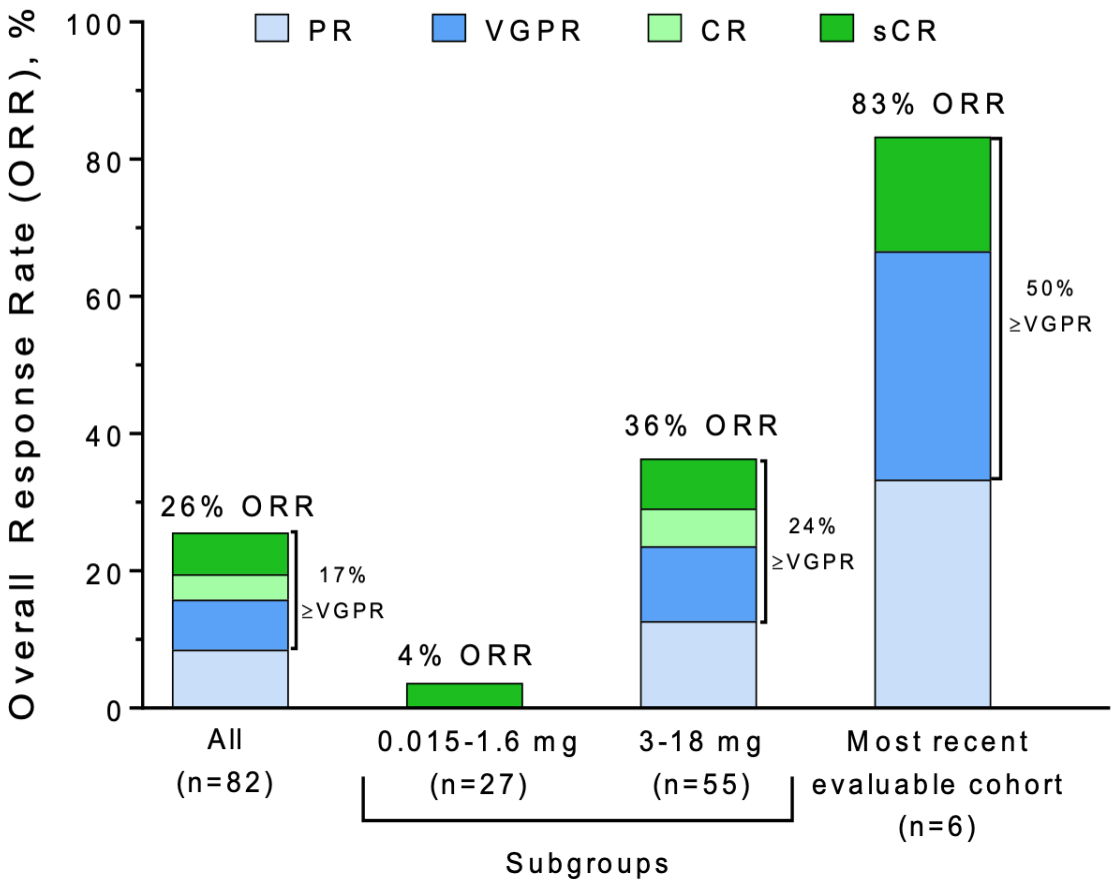
AMG 701 FIH: Overall Response Rate



Harrison et al. ASH 2020. Abstract #181

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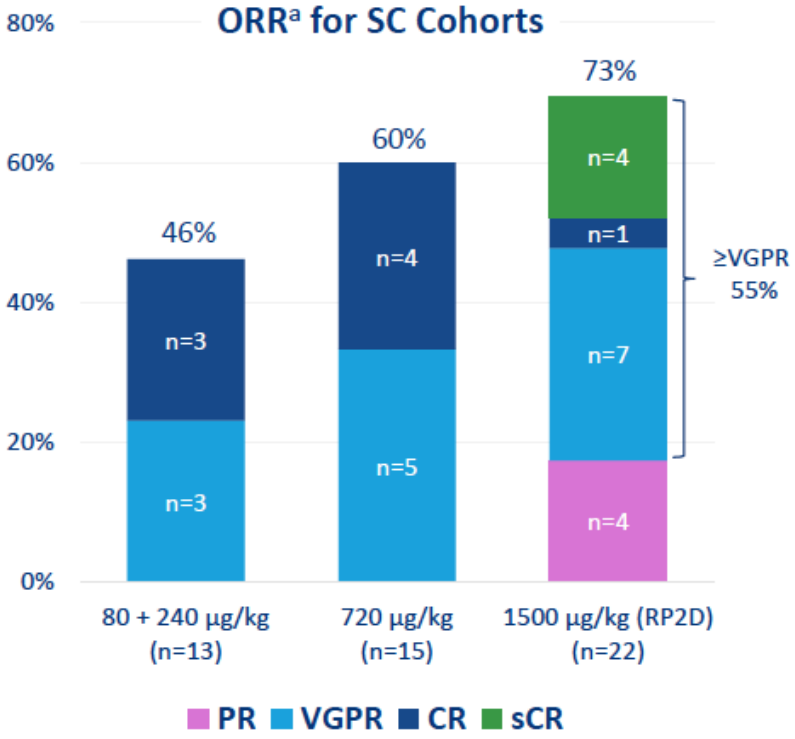
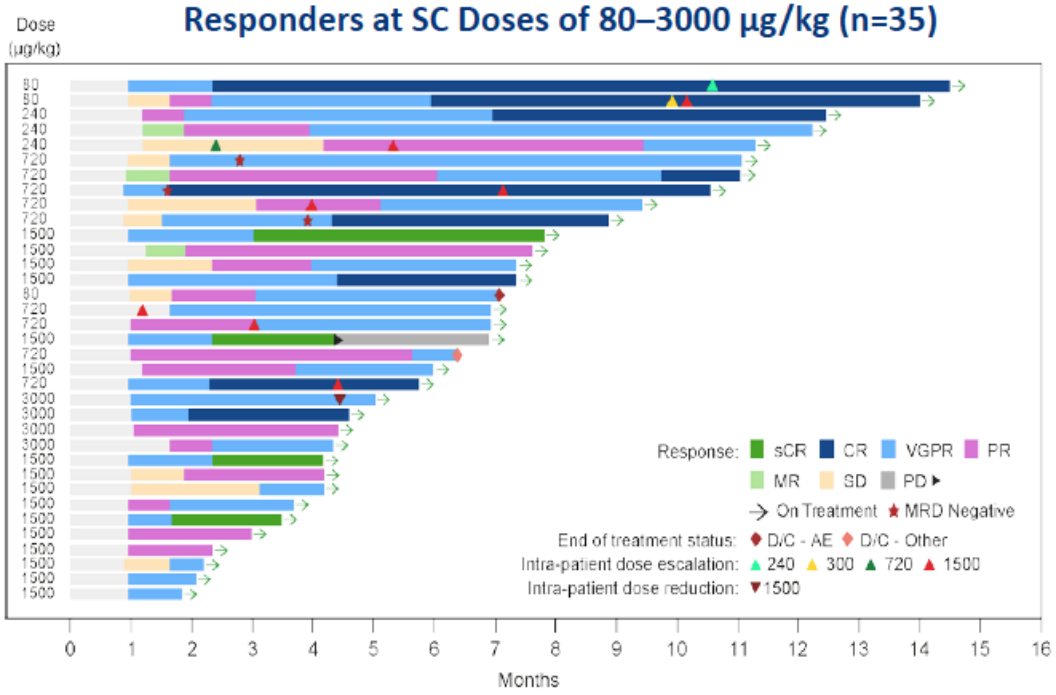
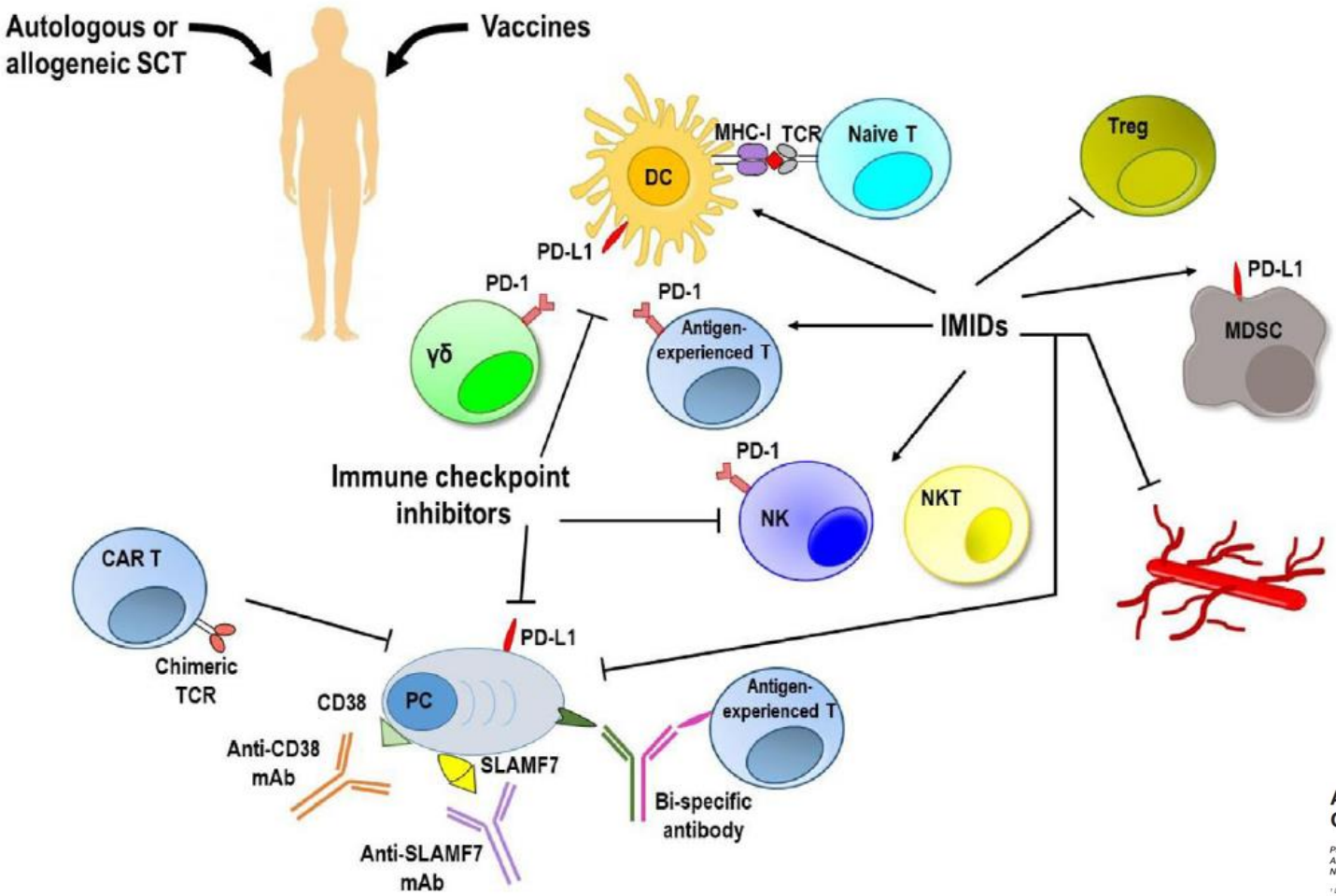
Teclistamab





Garfall et al. ASH 2020. #180

Multiples Myelom: Immuntherapie



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[1] Department of Biomedical Sciences and Human Oncology, University of Bari Medical School, Bari, Italy, [2] Department of Medical Oncology, IRCCS Istituto Tumori "Giovanni Paolo II" of Bari, Bari, Italy, [3] Bio-Proteomics Facility, Department of Translational Research, Centro di Riferimento Oncologico di Aviano (CRO) IRCCS, Aviano, Italy

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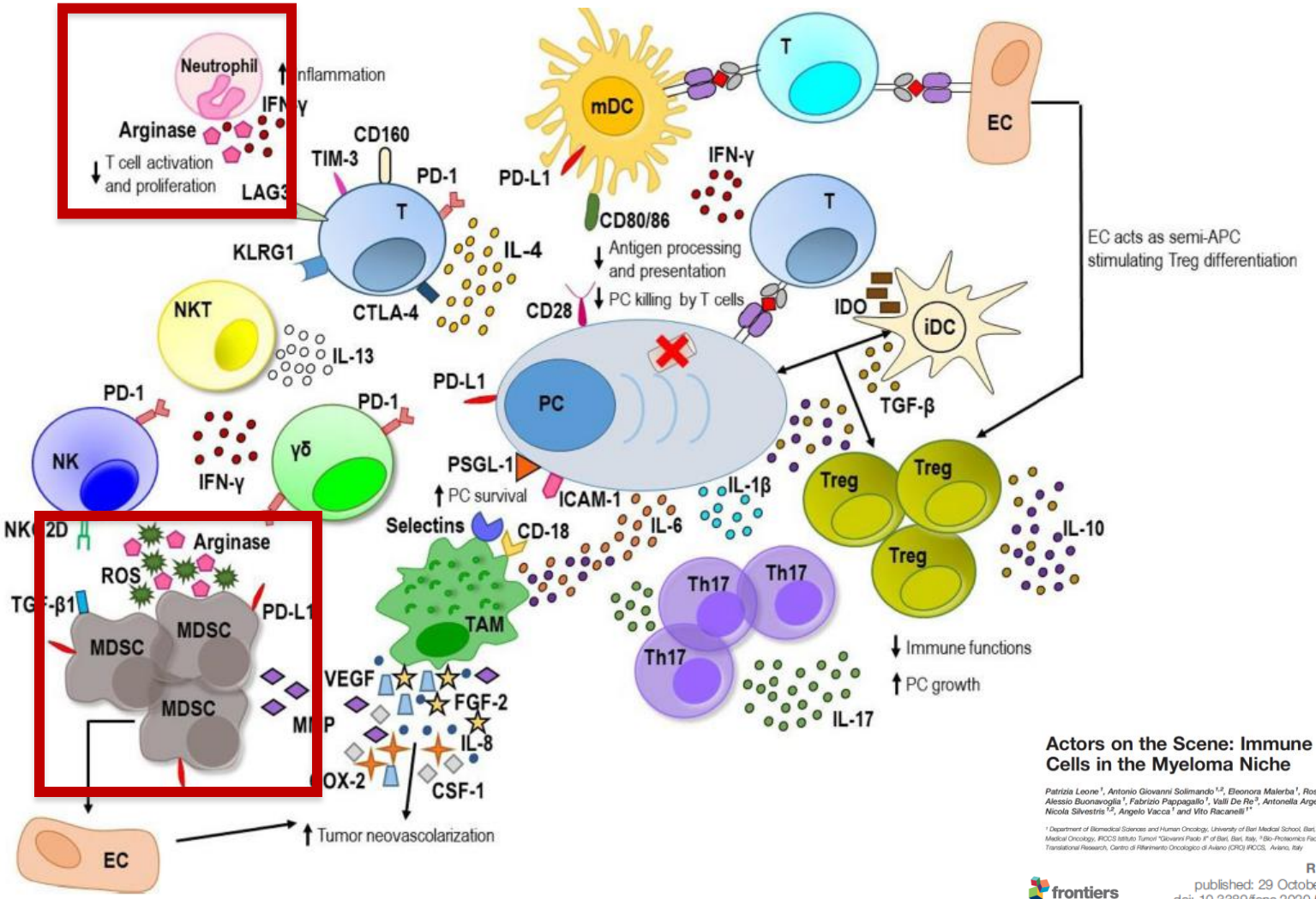
Immunzellen – MM Interaktionen

Knochenmarknische



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[1] Department of Biomedical Sciences and Human Oncology, University of Bari Medical School, Bari, Italy, [2] Department of Medical Oncology, IRCCS Istituto Tumori "Giovanni Paolo II" of Bari, Bari, Italy, [3] Bio-Proteomics Facility, Department of Translational Research, Centro di Riferimento Oncologico di Aviano (CRO) IRCCS, Aviano, Italy

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published: 29 October 2020
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Arginase-Inhibitor INCB1185
Klinische Entwicklung

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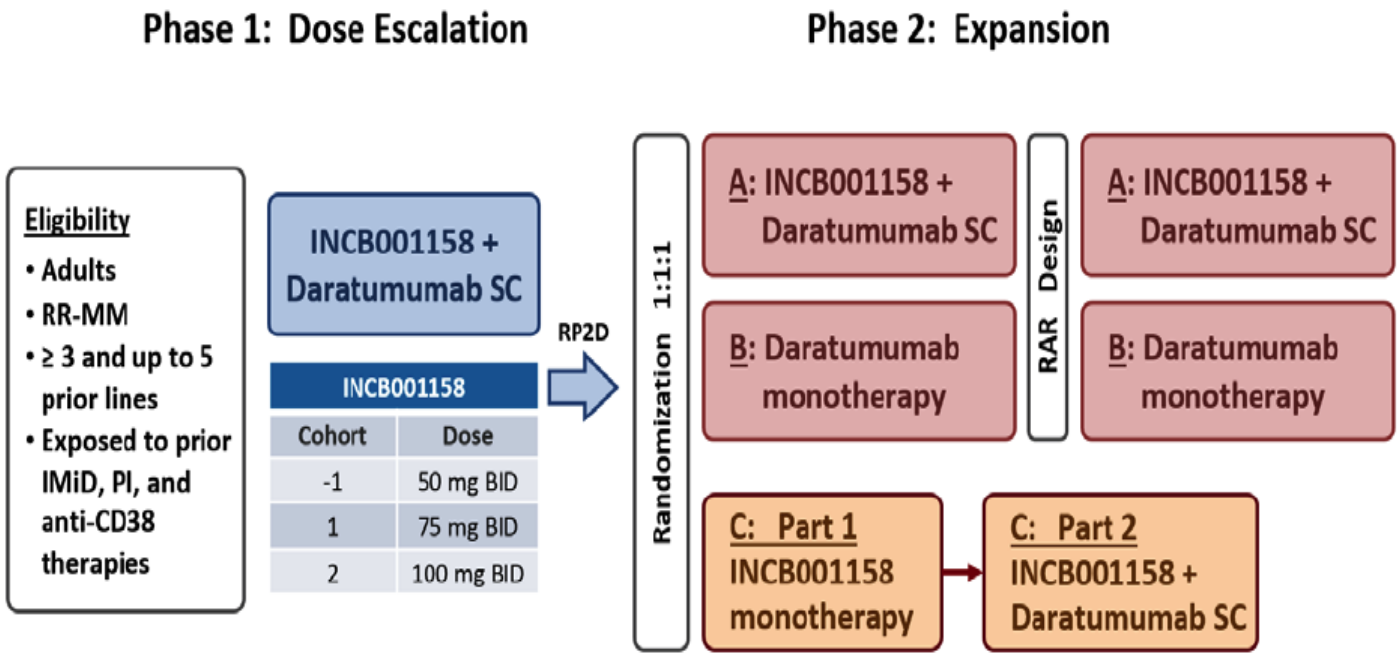
Studie offen / III. Med. Klinik

A Randomized Open-Label Phase 1/2 Study of INCB001158 Combined With Subcutaneous (SC) Daratumumab, Compared to Daratumumab SC, in Participants With Relapsed or Refractory Multiple Myeloma

EudraCT Nr.: 2018-004076-35 Protokoll Nr: INCB 01158-206
Sponsor: Incyte



Behandlungssequenzen 2021

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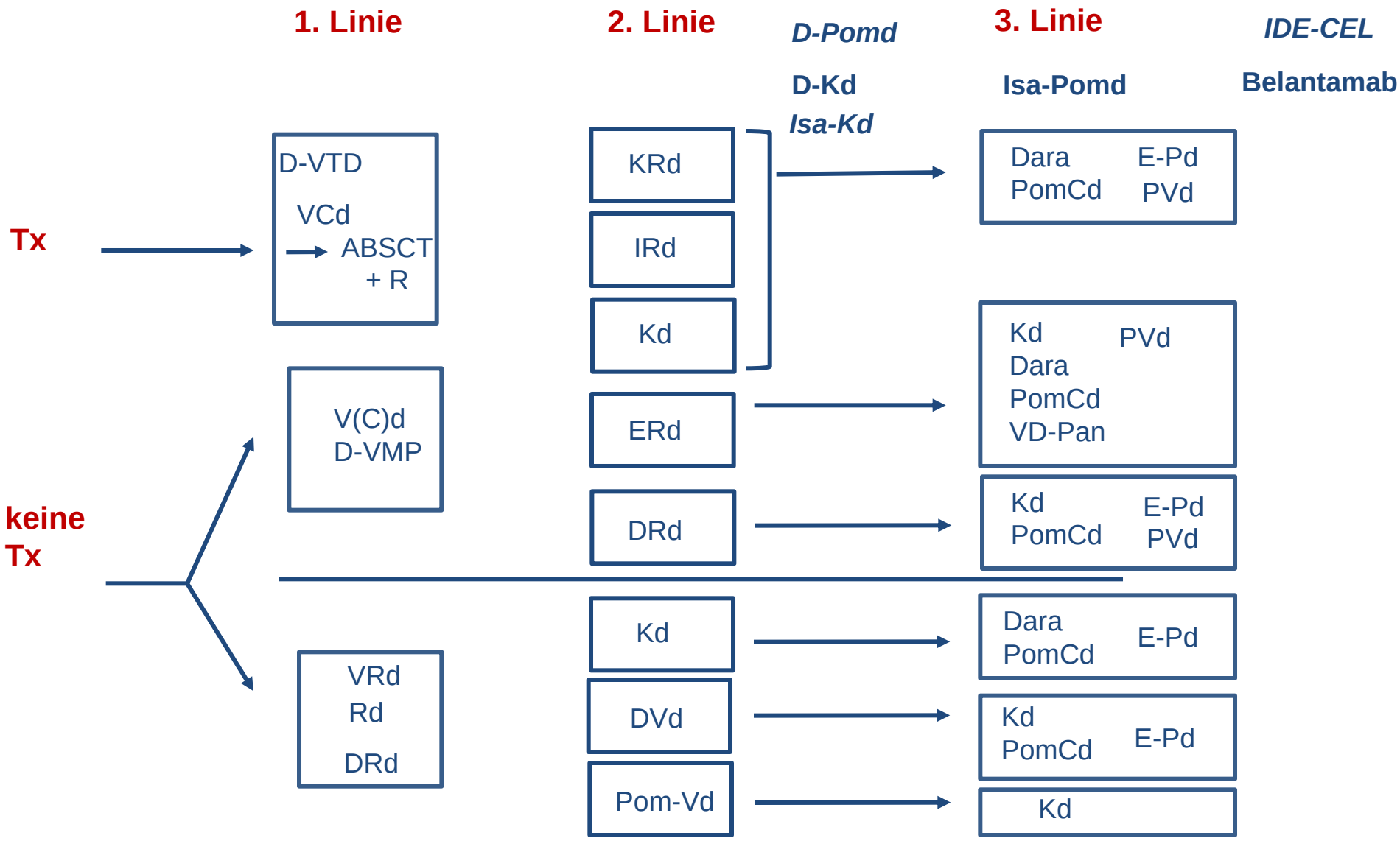
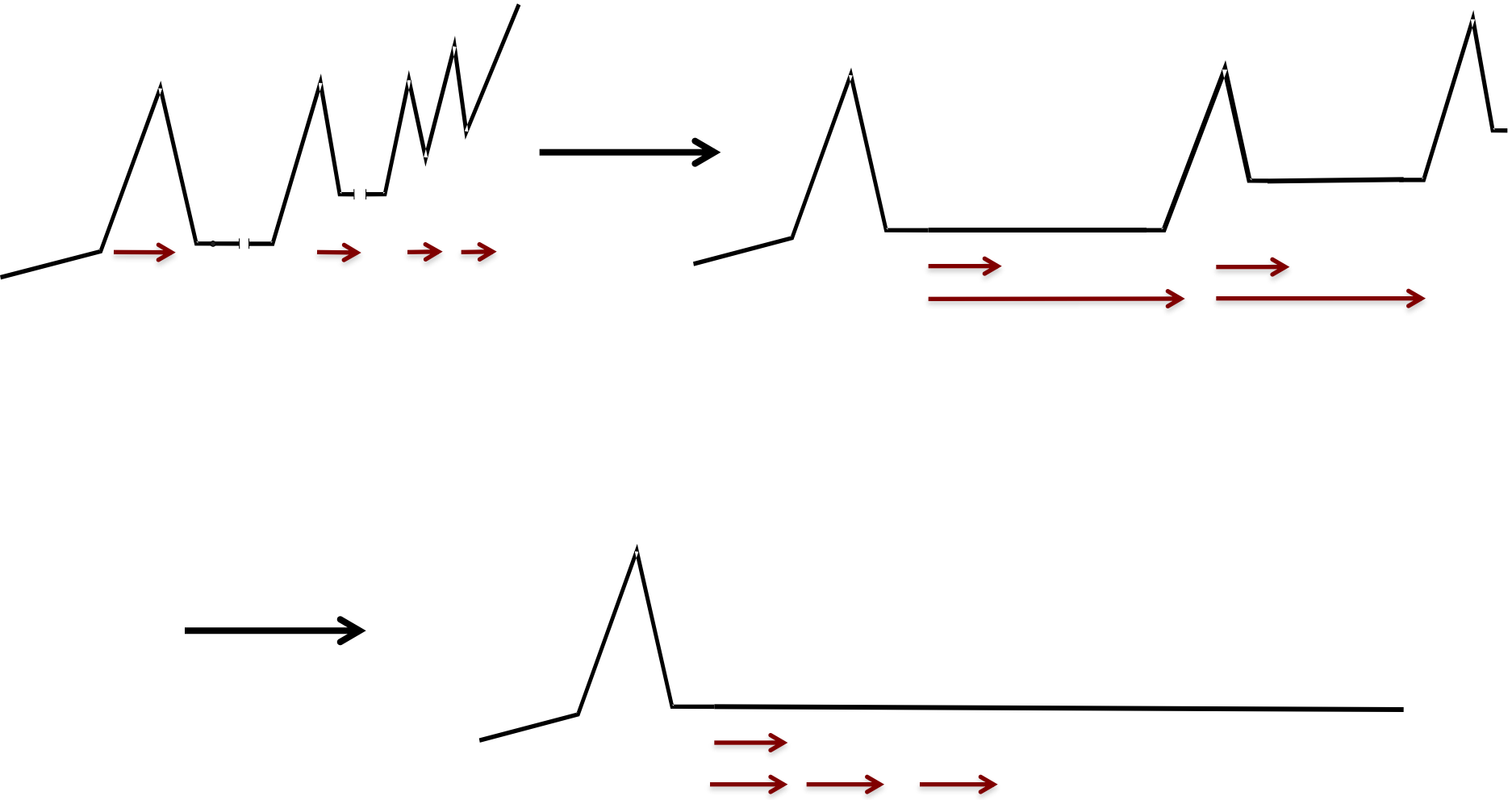


MM: Immuntherapie



Vielen Dank für Ihre Aufmerksamkeit!

Prof. Dr. med. Markus Munder
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