Amsterdam UMC
Universitair Medische Centra

Post-ASH 2020 webinar MPE

Multiple myeloma and AL amyloidosis

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16 december 2020

Content

Introduction

Newly diagnosed MM
- Transplant eligible / role of autologous stem cell transplant
- Non-transplant eligible

Relapsed/refractory MM (RRMM) - early relapse
- Based on IMID, PI, anti-CD38

Relapsed/refractory MM - late relapse
- Bispecifics
- CAR-T
- Antibody drug conjugates

AL amyloidosis

Take home messages

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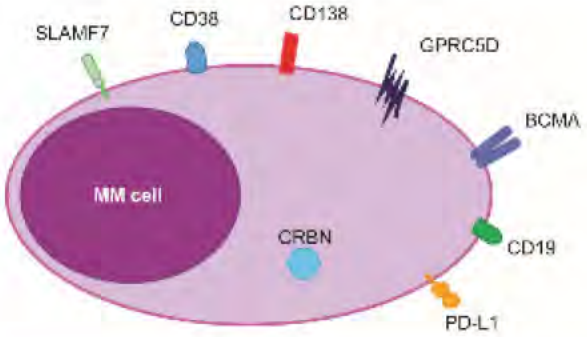
AL amyloidosis

Take home messages

Introduction



Classical "novel" agents

- **Immunomodulatory agents**
  - Thalidomide
  - Lenalidomide
  - Pomalidomide
- **Proteasome inhibitors**
  - Bortezomib
  - Carfilzomib
  - Ixazomib

Immunotherapy

- **Bispecific antibodies (BiTes)**
  - Teclistamab
  - Talquetamab
- **Antibody drug conjugates**
  - Belantamab-mafodotin
  - …
- **CAR-T cell therapy**
  - Ide-cel (bb2121)
  - Cilta-cel
  - And many more…
- **Other targeted therapies**
  - Panobinostat
  - Selinexor
  - Venetoclax
- **Anti-CD38 antibodies**
  - Daratumumab
  - Isatuximab

Introduction - study phases

Phase 1 → to evaluate **safety** of a new drug
- To find the RP2D: recommended phase 2 dose

Phase 2 → to further assess **safety**, as well the **effectiveness** of a new drug

Phase 3 → to compare the effectiveniss and safety of the new treatment **versus current treatment**

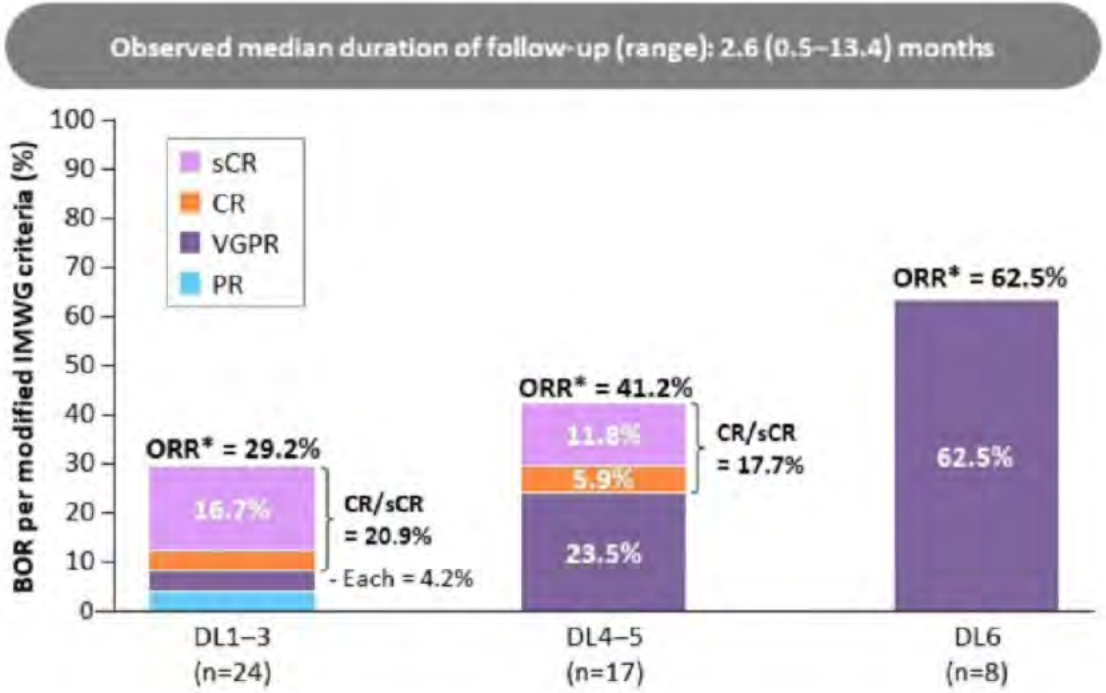
Based on the evidence of studies → EMA (European Medicines Agency) can approve drug(s)

Per country different timelines concerning approval and reimbursement of treatment regimens

Introduction

ORR is “overall response rate”

Including	Reduction M-protein
Partial response (PR)	50-90%
Very good partial response (VGPR)	90-99%
Complete response (CR)	100%
Stringent complete response (sCR)	when bone marrow clean
MRD = minimal residual disease	more sensitive



Madduri, paper ID 291

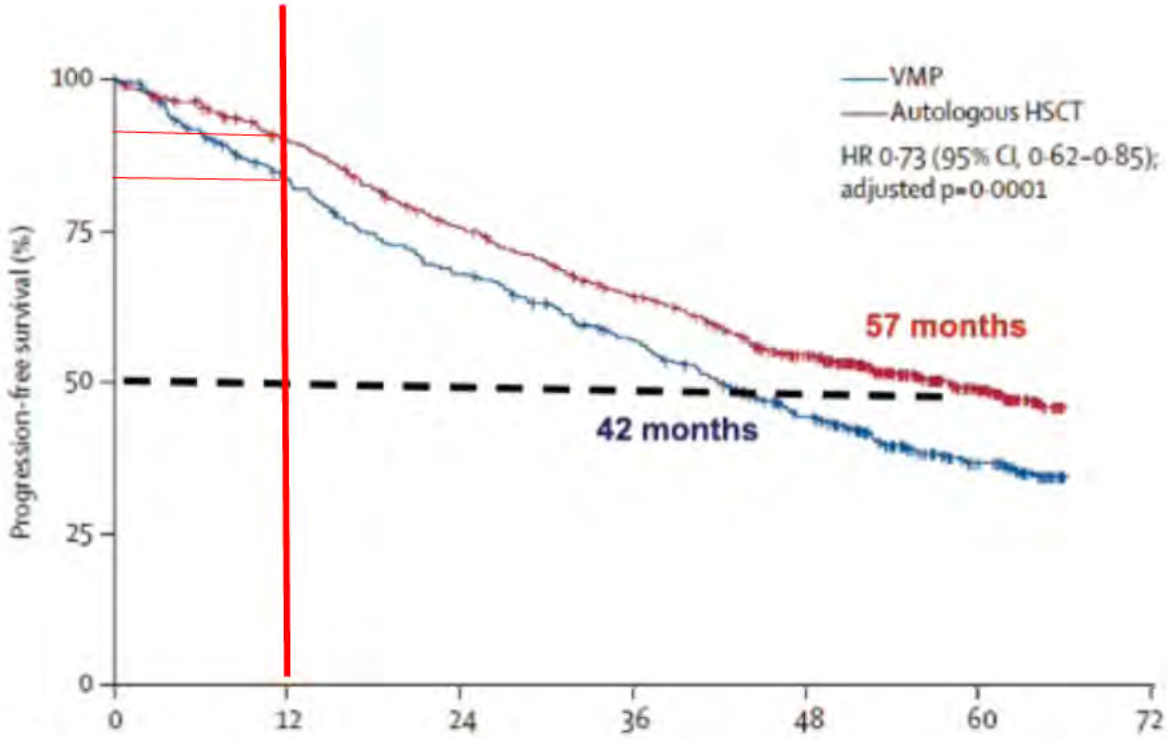
Introduction

PFS = progression free survival

- time from start treatment to disease progression or death

PFS curve

- Dotted line is median PFS
  (50% of patients alive without disease progression)
- Red vertical line is 12 months PFS
  (% of patients alive at 12 months without disease progression)



Number at risk (number censored)							
Autologous HSCT	702 (0)	616 (17)	509 (24)	428 (31)	334 (59)	178 (188)	..
VMP	495(0)	401 (13)	324 (14)	266 (21)	189 (39)	97 (104)	..

Cavo, Paper ID 142

Introduction

To classify side effects:

- Grade 1 / 2: relative mild
- Grade 3 / 4: more severe
- Grade 5: death

Highlighting the highlights of ASH 2020

Therapies for newly diagnosed MM

Therapies for relapsed and refractory MM

Preclinical studies (not in human)

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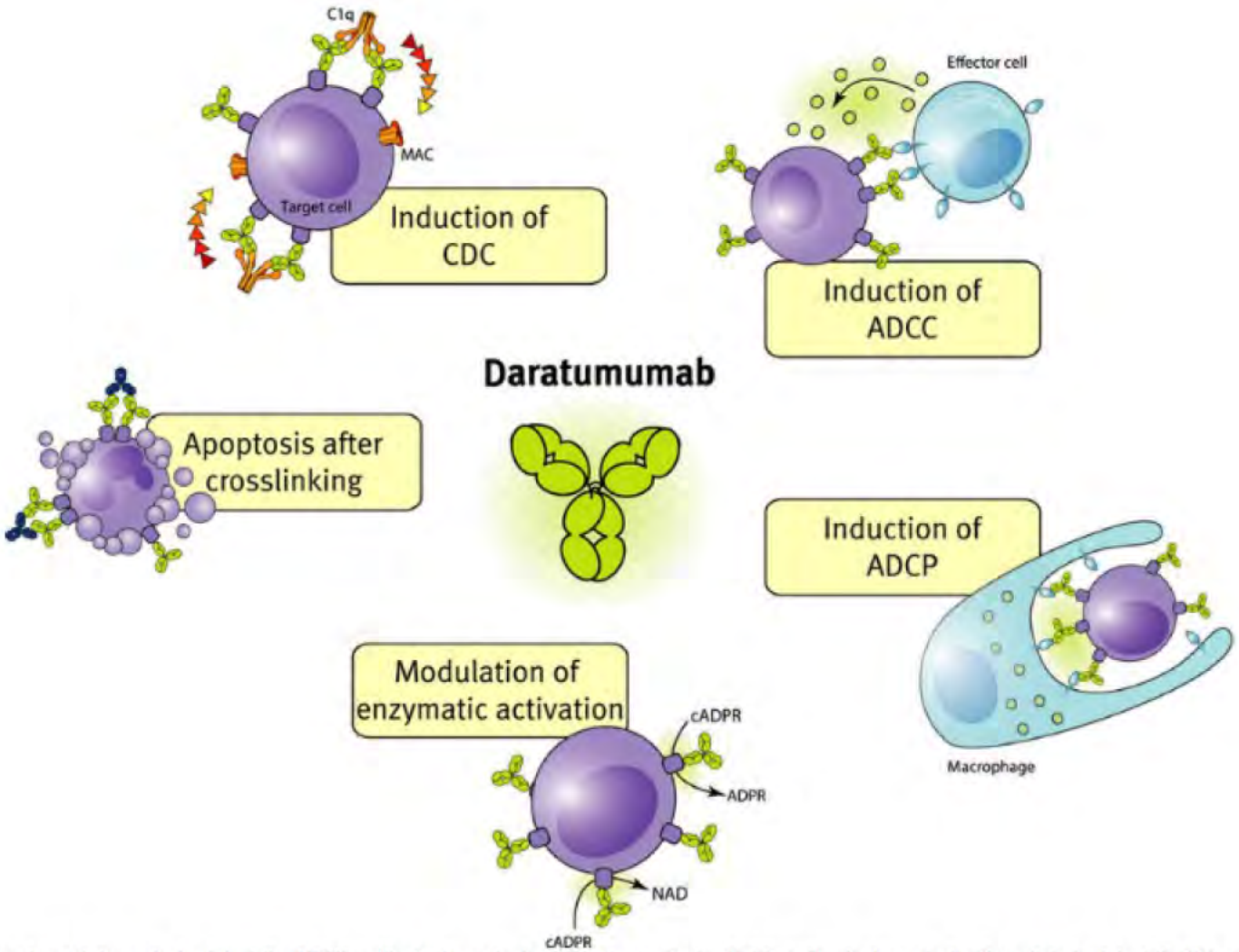

Phase 3 Trials

RRMM

- D-Rd (POLLUX)
- D-Vd (CASTOR)
- D-Pd (APOLLO)
- D-Kd (CANDOR)

NDMM non-transplant

- D-Rd (MAIA)
- D-VMP (ALCYONE)
- D-VRd (CEPHEUS)*

NDMM transplant

- D-VTd Part 1 (CASSIOPEIA)
  - D maintenance Part 2
- D-VRd (PERSEUS)*
  - D-R maintenance[a]
- D-R maintenance (AURIGA)*

*Pending results.
[a]Discontinue D if MRD negative.

CDC, complement-dependent cytotoxicity; ADCP, antibody-dependent cellular phagocytosis; ADCC, antibody-dependent cell-mediated cytotoxicity; NK, natural killer; RRMM, relapsed/refractory multiple myeloma; D, daratumumab; R, lenalidomide; d, dexamethasone; V, bortezomib; P, pomalidomide; K, carfilzomib; NDMM, newly diagnosed multiple myeloma; MP, melphalan and prednisone; T, thalidomide; SC, subcutaneous; MRD, minimal residual disease. 1. DARZALEX® (daratumumab) injection, for intravenous use [package insert]. Horsham, PA: Janssen Biotech, Inc.; 2020. 2. Liszewski MK, et al. *Adv Immunol*. 1996;61:201-283. 3. Debets JM, et al. *J Immunol*. 1988;141(4):1197-1201. 4. Overdijk MB, et al. *MAbs*. 2015;7(2):311-321. 5. Lokhorst HM, et al. *N Engl J Med*. 2015;373(13):1207-1219. 6. Plesner T, et al. Oral presentation at: ASH; December 8-12, 2012; Atlanta, GA. Abstract 73. 7. Krejcik J, et al. *Blood*. 2016;128(3):384-394. 8. Adams HC 3rd, et al. *Cytometry A*. 2019;95(3):279-289. 9. Casneuf T, et al. *Leukemia*. 2020 May 26;doi: 10.1038/s41375-020-0855-4; [E-pub ahead of print].

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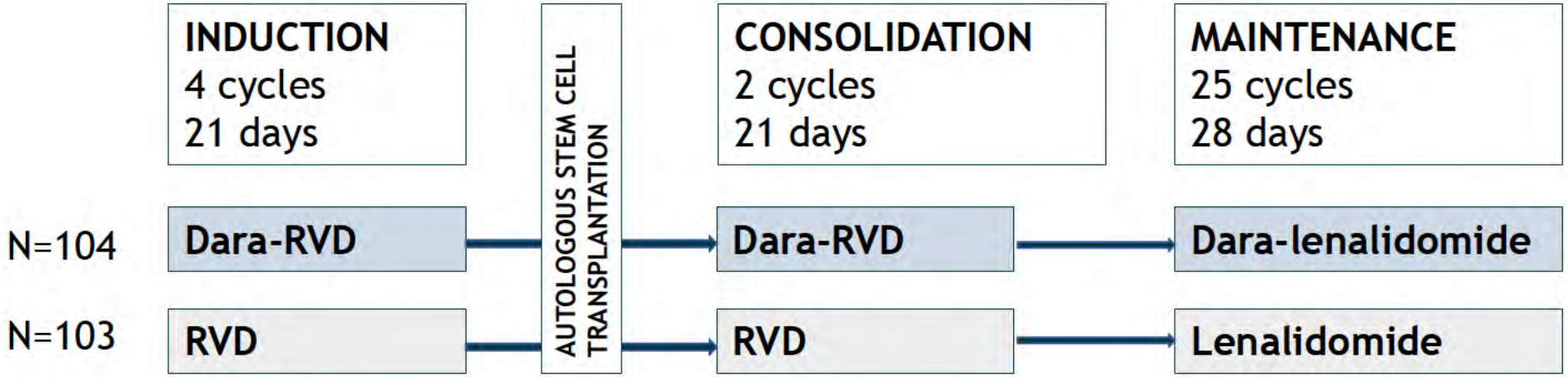
Newly diagnosed MM
Transplant eligible

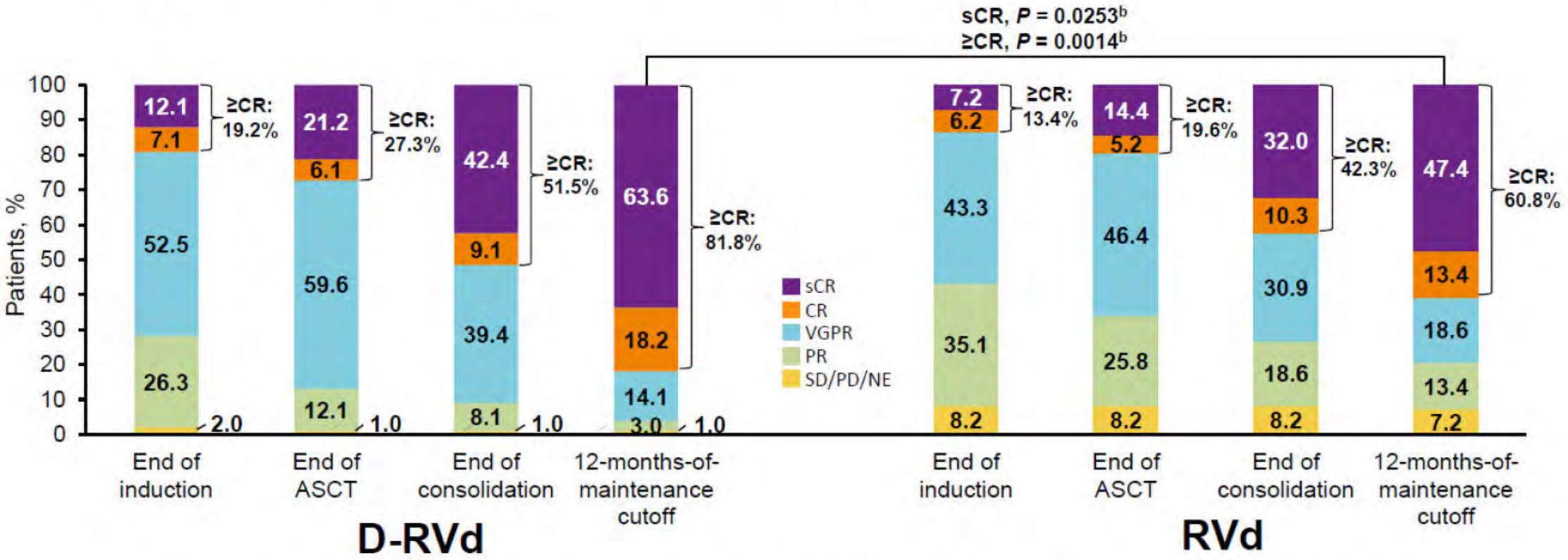
GRIFFIN trial: dara-RVD vs RVD



Dara: daratumumab; N: number; RVD: lenalidomide-bortezomib-dexamethasone

Kaufman, Paper ID 549

Responses Deepened over Time[a]



- *Results for end of induction, ASCT, and consolidation are based on a median follow up of 13.5 months at the primary analysis*
- *Median follow up at 12-months-of-maintenance therapy cutoff was 27.4 months*

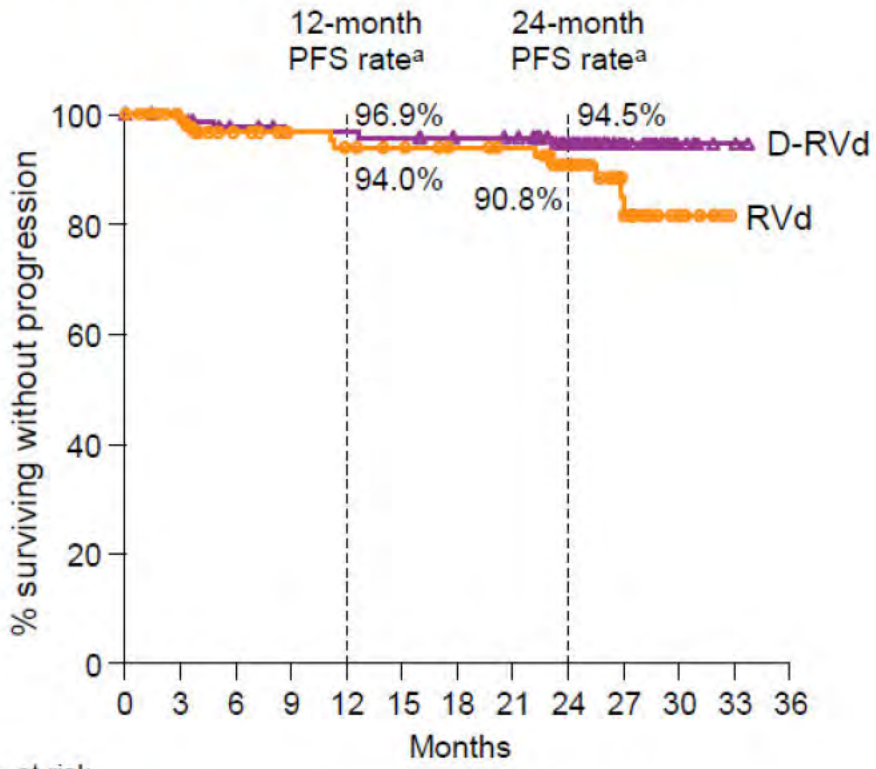
Response rates and depths were greater for D-RVd at all time points

PR, partial response. SD/PD/NE, stable disease/progressive disease/not evaluable. [a]Data are shown for the response-evaluable population. [b]*P* values (2-sided) were calculated using the Cochran–Mantel–Haenszel chi-square test.

Kaufman, Paper ID 549

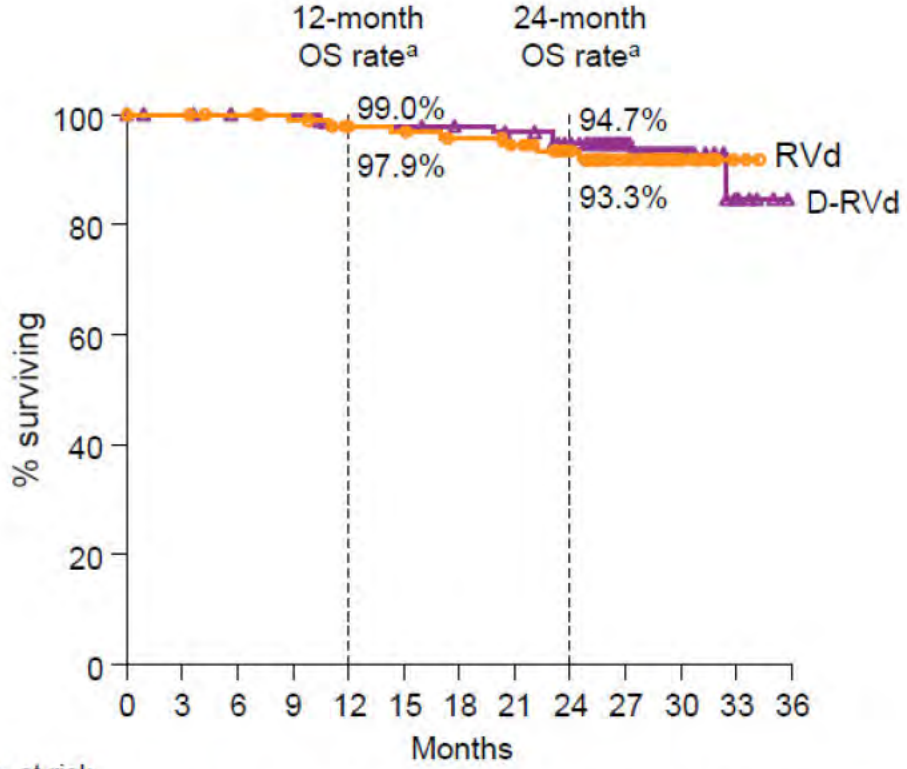
PFS and OS in the ITT Population

- Median follow-up = 27.4 months



No. at risk

RVd	103	93	77	71	68	66	62	60	52	23	7	0	0
D-RVd	104	98	93	89	89	88	86	86	66	32	9	2	0



No. at risk

RVd	103	101	98	95	89	87	84	81	67	46	14	2	0
D-RVd	104	100	98	98	96	95	93	91	85	61	23	6	0

Median PFS and OS were not reached for D-RVd and RVd

OS, overall survival. [a]Kaplan–Meier estimate.

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Take home messages

Newly diagnosed MM

Transplant eligible – role of autologous stem cell transplantation

Is there still a role for autologous stem cell transplant?

I. FORTE trial

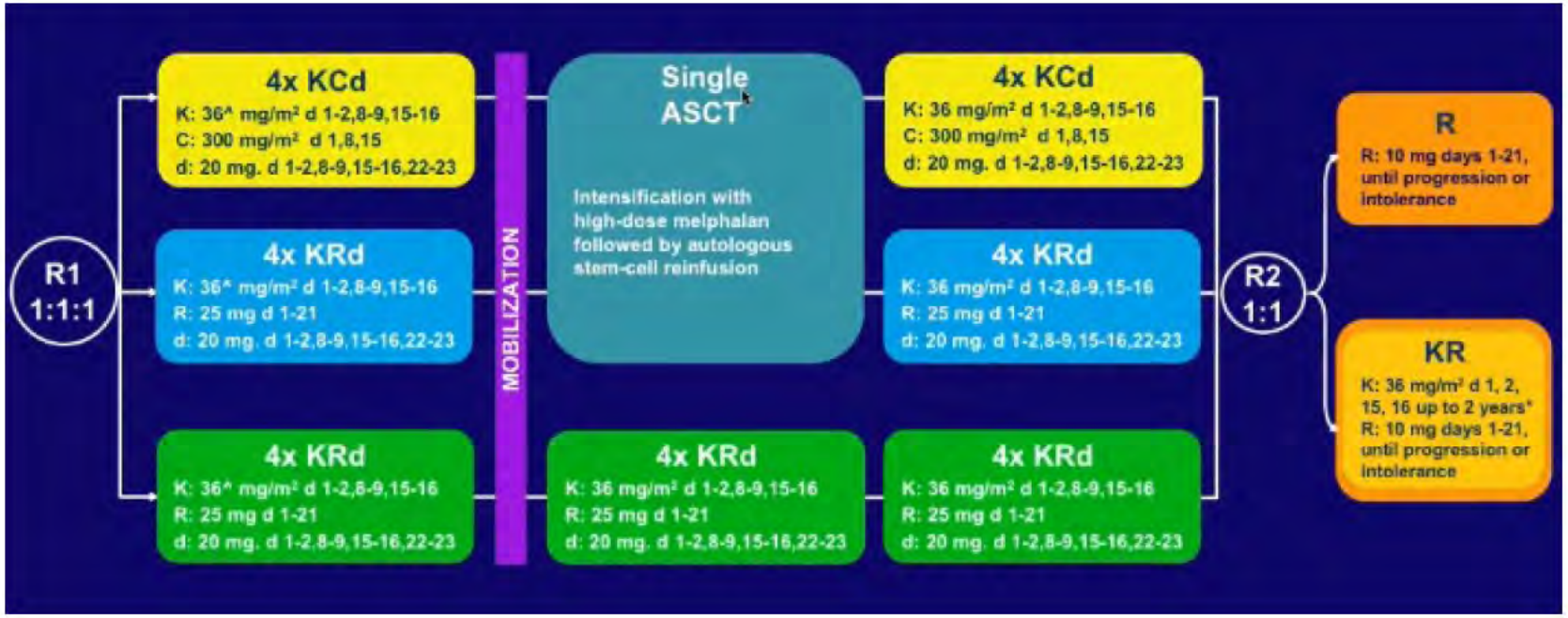
II. Long term follow-up EMN-2/HOVON95 study

III. IFM 2009 trial – long term follow-up

Newly diagnosed MM

Transplant eligible – role of autologous stem cell transplantation

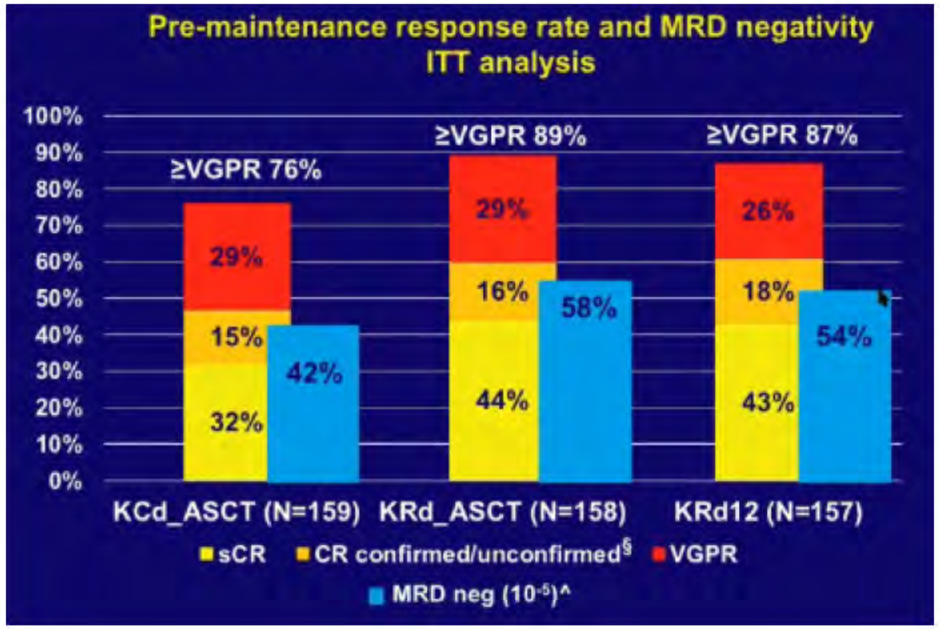
Forte trial: 474 patients, < 65 years

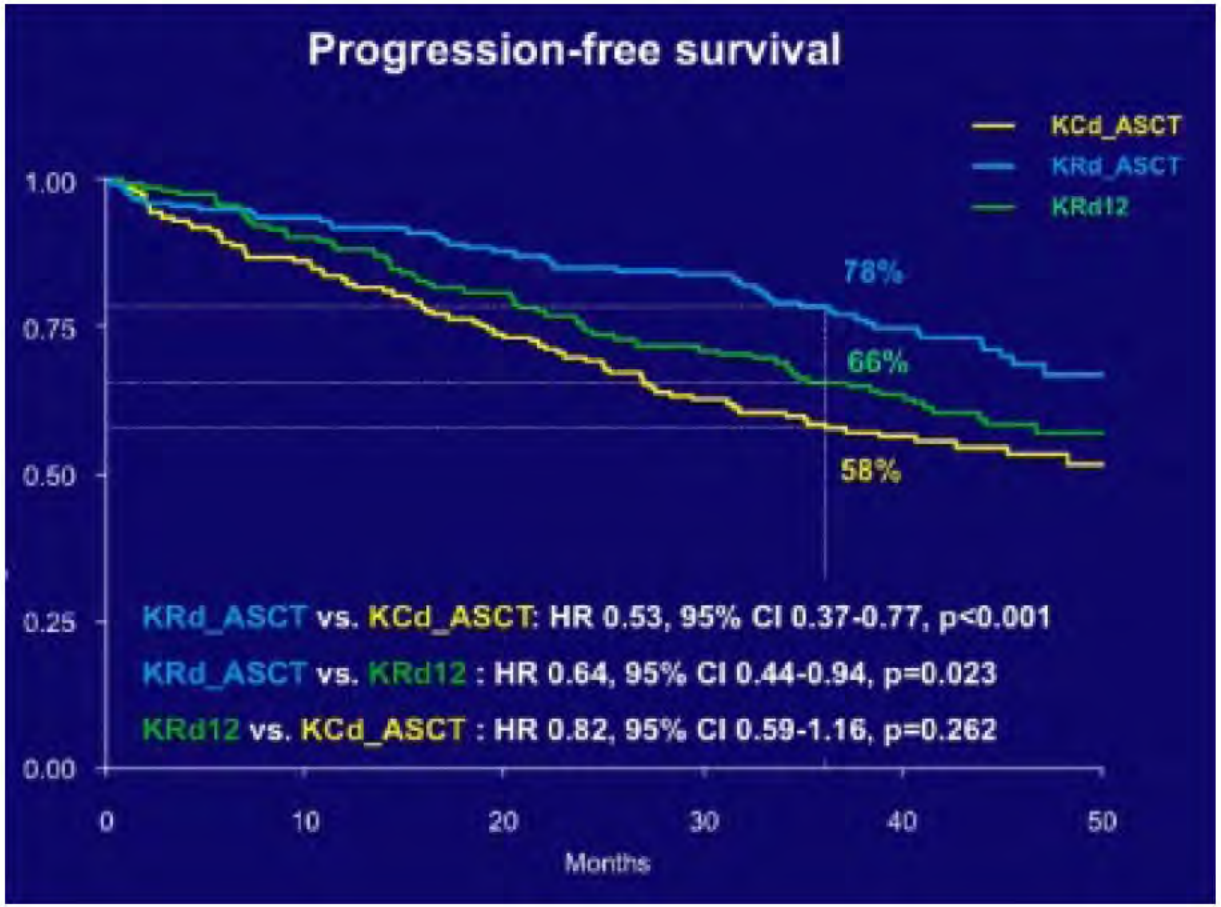


Gay, paper ID 141

Newly diagnosed MM

Transplant eligible – role of autologous stem cell transplantation





Gay, paper ID 141

Newly diagnosed MM

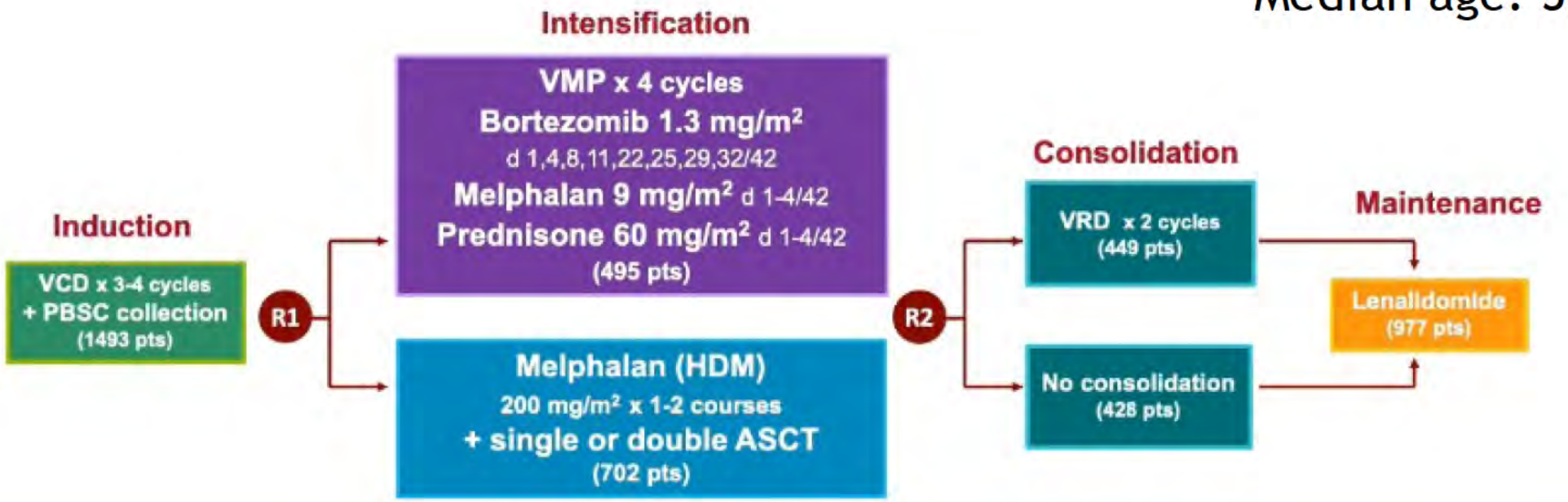
Transplant eligible – role of autologous stem cell transplantation

Long term follow-up EMN-2/HOVON95 study

Arm VMP: 495 pt

Arm HDM: 702 pt

Median age: 58y



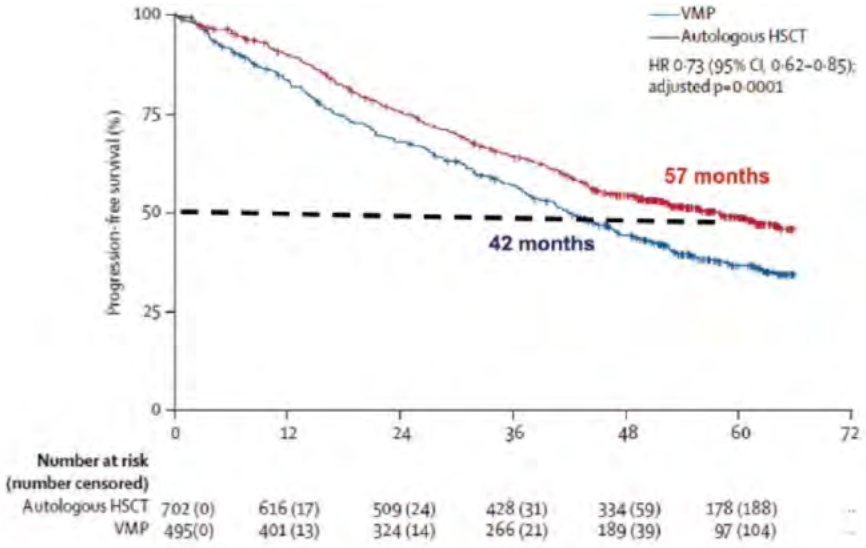
Cavo, paper ID 142

Newly diagnosed MM

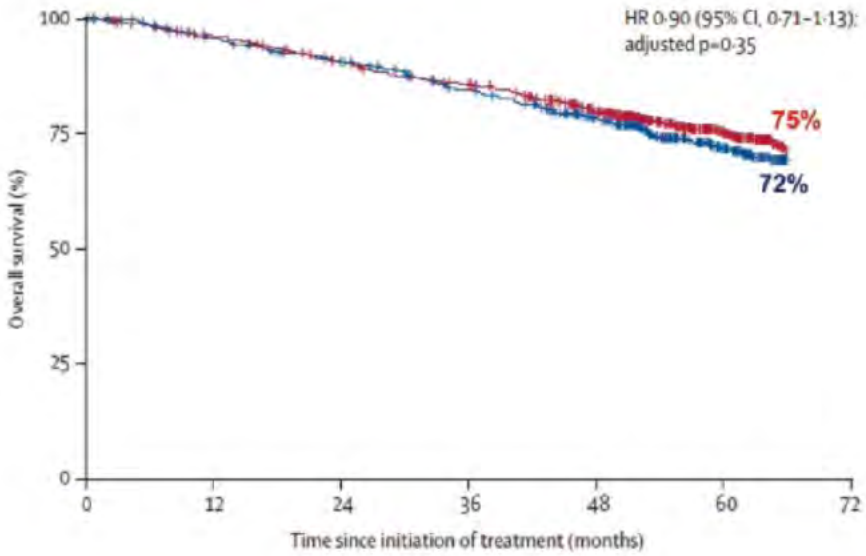
Transplant eligible – role of autologous stem cell transplantation

Long term follow-up EMN-2/HOVON95 study

PFS



OS



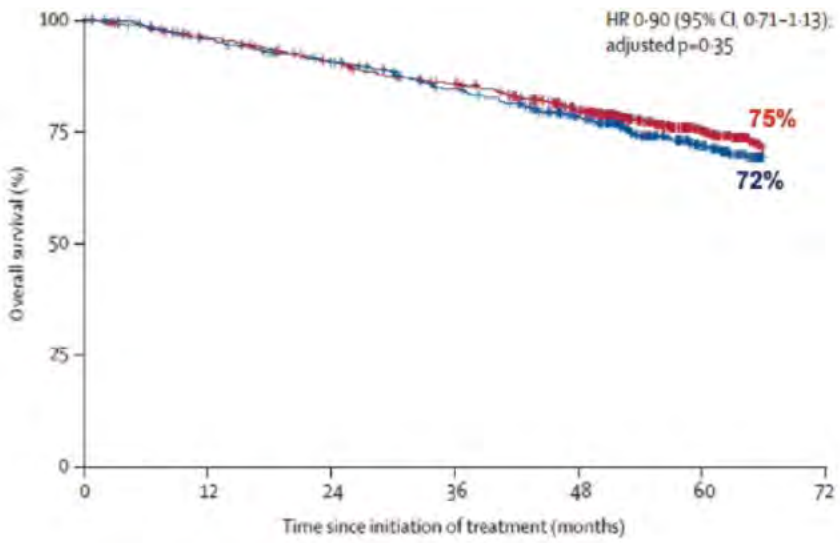
Cavo, paper ID 142

Newly diagnosed MM

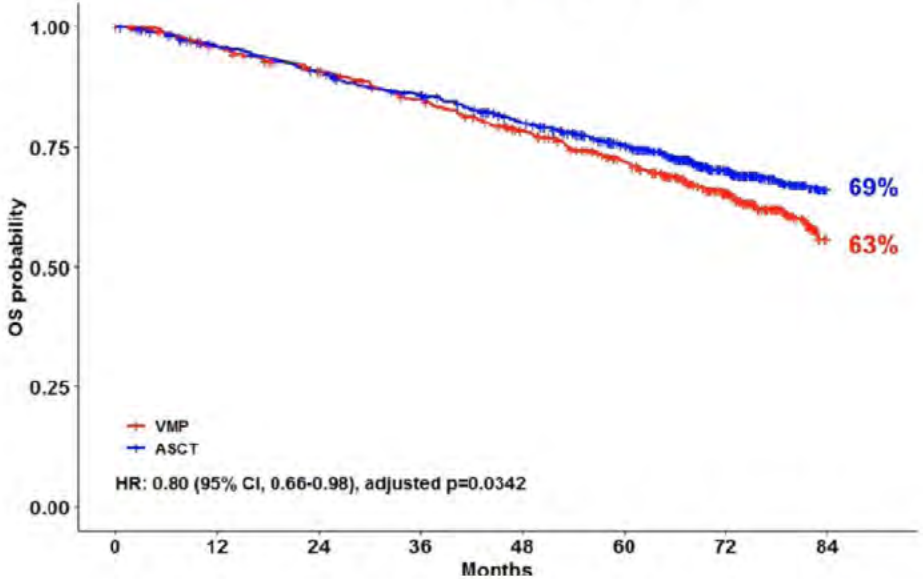
Transplant eligible – role of autologous stem cell transplantation

Long term follow-up EMN-2/HOVON95 study

OS



OS longer FU



Cavo, paper ID 142

Newly diagnosed MM

Transplant eligible – role of autologous stem cell transplantation

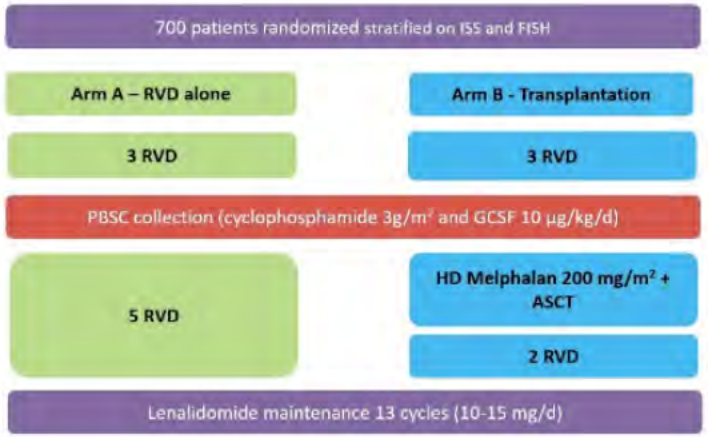
IFM 2009 trial – long term follow-up

Arm A: 8x RVD, followed by lenalidomide maintenance

Arm B: 3x RVD + HDM/ASCT + 2x RVD, followed by lenalidomide maintenance

Interim analysis at 44months follow-up:

Median PFS 36 vs 50 months

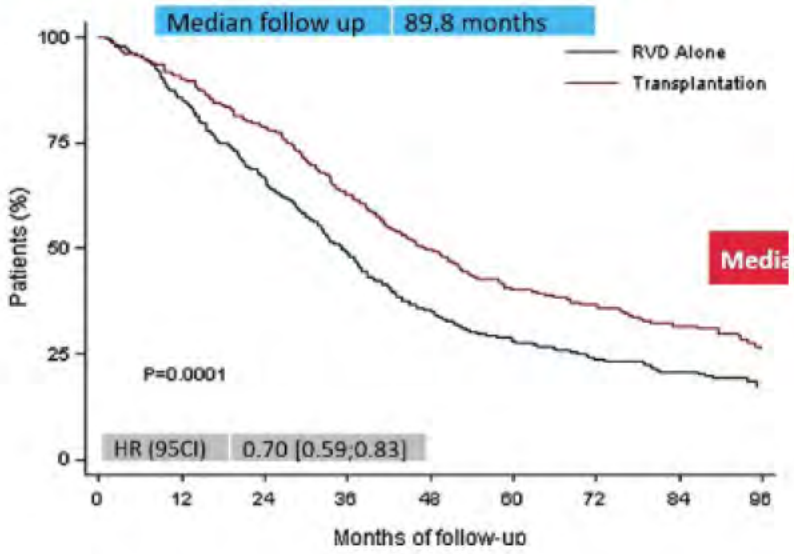


Perrot, paper ID 143

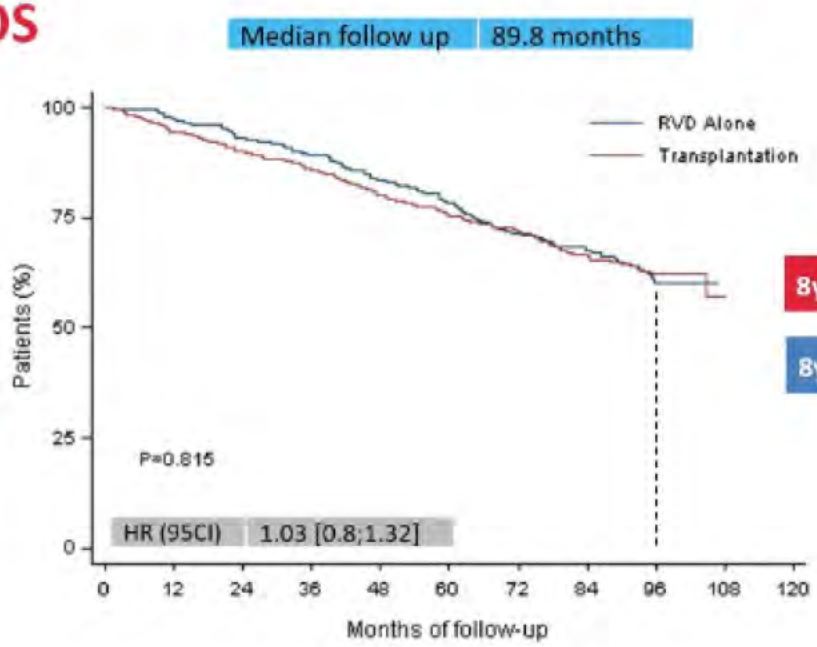
Newly diagnosed MM

Transplant eligible – role of autologous stem cell transplantation

Updated PFS (primary endpoint)



OS



8y-OS 62.2% (Transplantation, arm B)

8y-OS 60.2% (RVD alone, arm A)

Perrot, paper ID 143

Newly diagnosed MM

Transplant eligible – role of autologous stem cell transplantation

Is there still a role for autologous stem cell transplant?

I. FORTE trial YES

II. Long term follow-up EMN-2/HOVON95 study YES

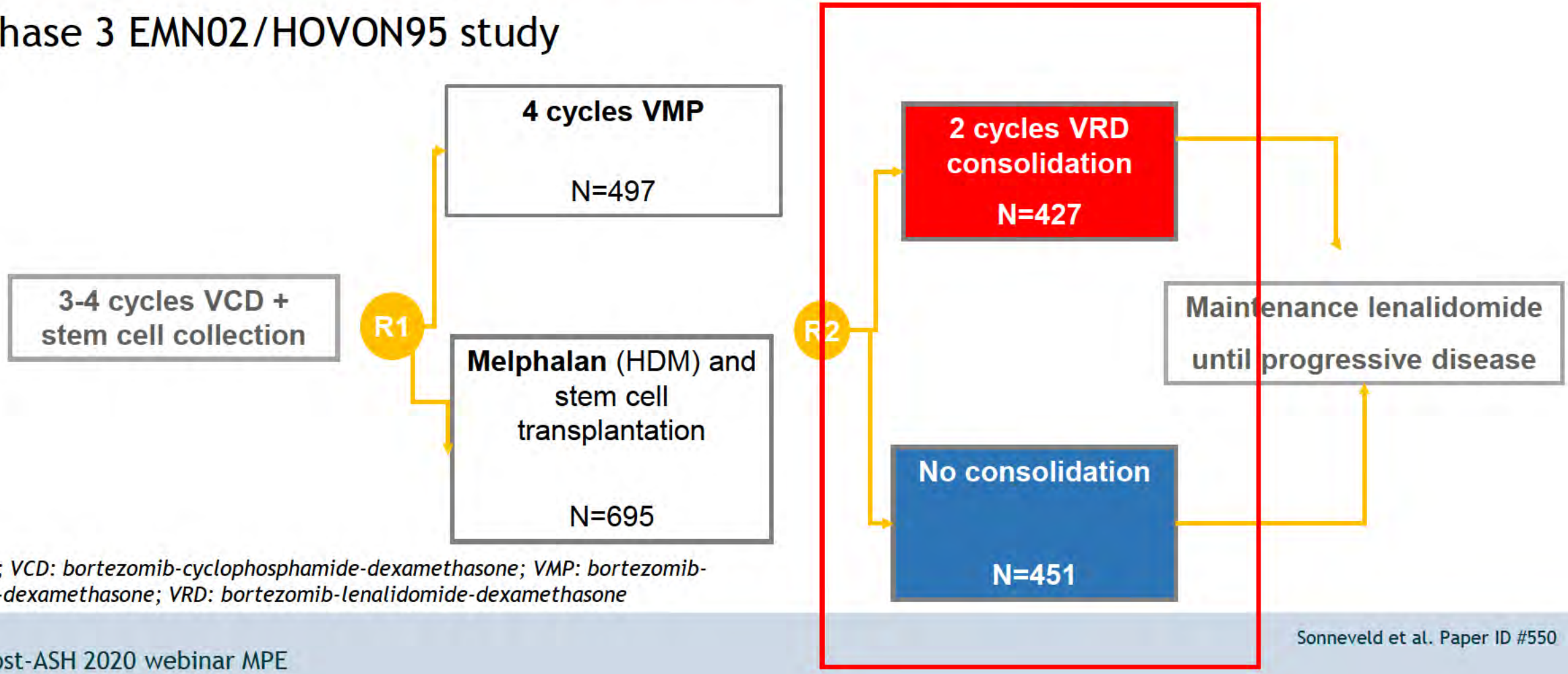
III. IFM 2009 trial – long term follow-up YES

Note: these studies don't contain daratumumab → effect on role ASCT?

Newly diagnosed MM

Transplant eligible - consolidation treatment

Phase 3 EMN02/HOVON95 study

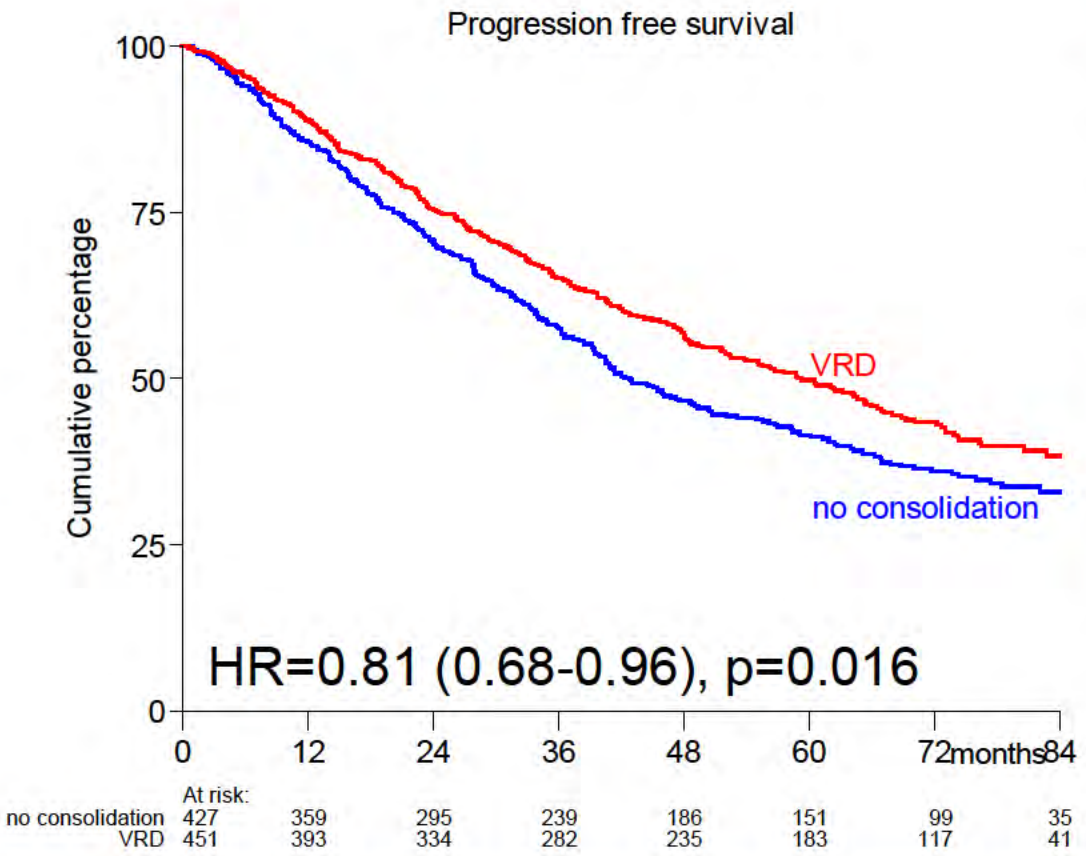


N: number; VCD: bortezomib-cyclophosphamide-dexamethasone; VMP: bortezomib-melphalan-dexamethasone; VRD: bortezomib-lenalidomide-dexamethasone

Sonneveld et al. Paper ID #550

Newly diagnosed MM

Transplant eligible - consolidation treatment



	no consolidation	VRD
Patients #	**427**	**451**
Best response %		
sCR	**23**	**35**
CR	**23**	**24**
VGPR	**41**	**30**
≤ PR	**14**	**11**

46%

59%

Difference in (s)CR rate: p<0.001

Sonneveld et al. ORAL Paper ID 550

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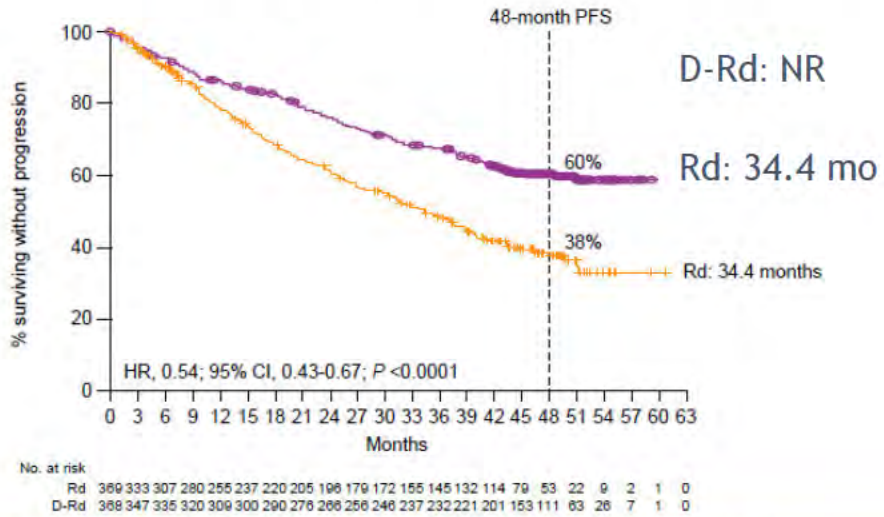
AL amyloidosis

Take home messages

Newly diagnosed MM
Non-transplant eligible

Dara-Rd vs Rd (MAIA)[1]

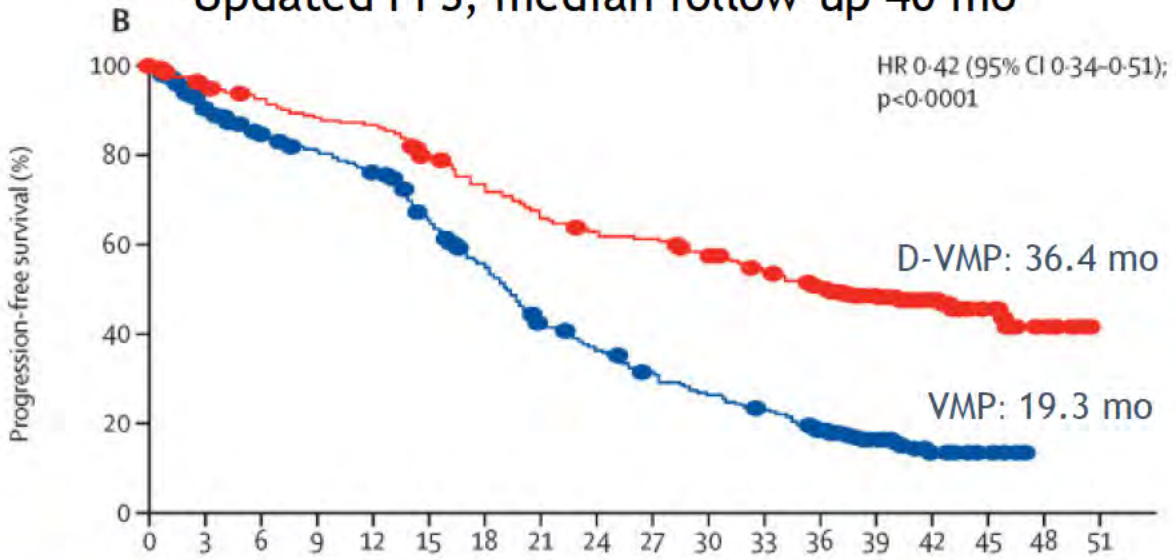
Updated PFS, median follow-up 48 mo



D-Rd demonstrated a significant benefit in PFS, with a 46% reduction in the risk of progression or death

Dara-VMP vs VMP (ALCYONE)[2]

Updated PFS, median follow-up 40 mo



D-VMP demonstrated a significant benefit in PFS, with a 58% reduction in the risk of progression or death

Dara: daratumumab; Rd: lenalidomide-dexamethasone; VMP: bortezomib-melphalan-prednisone

1. Kumar et al. Poster Paper ID 2276
2. Mateos et al. The Lancet 2020

Daratumumab subcutaneous versus intravenously

(A) RRMM with 1 prior line of therapy		(B) RRMM with ≥1 prior line of therapy		(C) Transplant-ineligible NDMM	
Median follow-up		Median follow-up		Median follow-up	
Primary	CANDOR[b]	Update	POLLUX[c]	Update	ALCYONE[d]
9.2 mo	~17 mo	25.7 mo	54.8 mo	25.2 mo	40.1 mo

Daratumumab subcutaneous versus intravenously:

- **At least similar response rates**
- **Reduced administration time**
- **Lower rates of infusion related reactions**

Therefore: advantage of subcutanous administration

American Society of Hematology

ORR, overall response rate; D-Kd, daratumumab subcutaneous plus carfilzomib/dexamethasone; Kd, carfilzomib/dexamethasone; D-Rd, daratumumab subcutaneous plus lenalidomide/dexamethasone; Rd, lenalidomide/dexamethasone; D-VMP, daratumumab subcutaneous plus bortezomib/melphalan/prednisone; VMP, bortezomib/melphalan/prednisone; DARA IV, daratumumab intravenous; RRMM, relapsed or refractory multiple myeloma; NDMM, newly diagnosed multiple myeloma; PR, partial response; VGPR, very good partial response; CR, complete response; sCR, stringent complete response.
[a]All-treated population, defined as patients who received ≥1 dose of study treatment. [b]Dimopoulos M, et al. *Lancet*. 2020;395(10245):186-197. [c]Kaufman JL, et al. Presented at: 61st American Society of Hematology (ASH) Annual Meeting & Exposition; December 7-10, 2019; Orlando, FL. Abstract 1866. [d]Mateos MV, et al. *Lancet*. 2020;395(10218):132-141. [e]In CANDOR, sCR could not be differentiated due to lack of kappa/lamda ratio by immunohistochemistry.

Moreau PLEIADES phase II study POSTER Paper ID 1380

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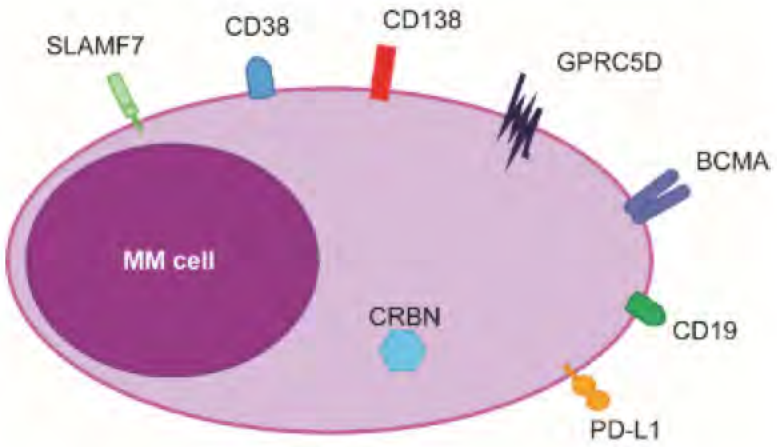
Take home messages

Relapse/refractory MM (RRMM) - early relapse
Based on IMID, PI, anti-CD38

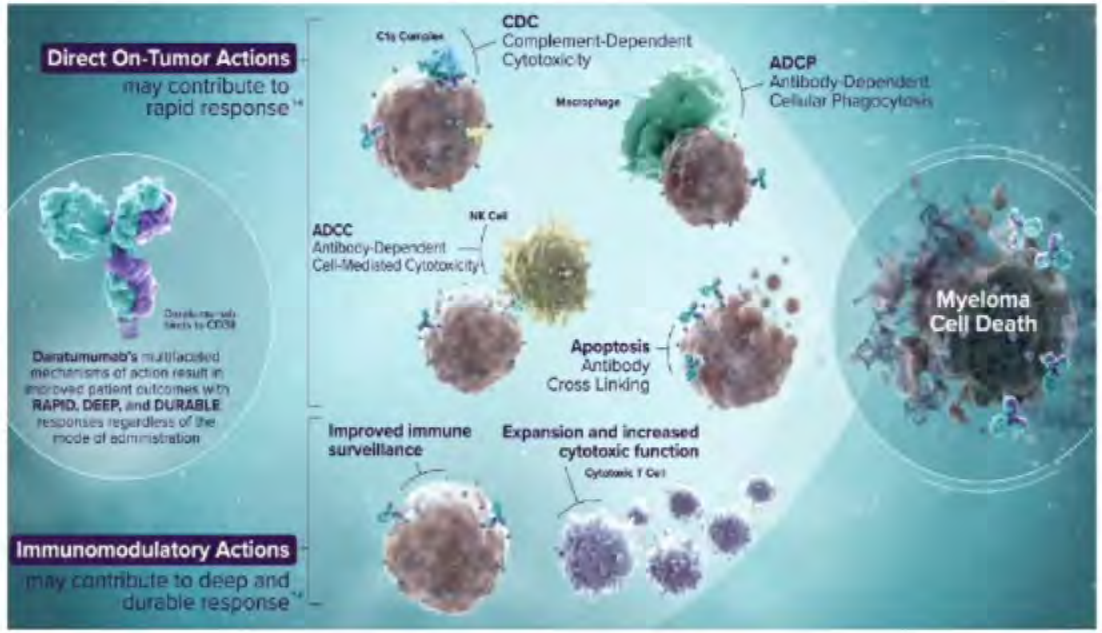
Three studies to discuss:

Apollo study	Dara-pom-dex	vs	Pom-dex
CMRG04 study	Dara-dex-cyclo-pom	vs	Dara-dex-cyclo
Ikema study	Isa-car-dex	vs	Car-dex



Dimopoulos, paper ID 412

Relapsed/refractory MM (RRMM)
Based on IMID, PI, anti-CD38



Apollo study - Phase 3:

A: Daratumumab SC + pomalidomide + dexamethason
vs
B: Pomalidomide + dexamethason

RRMM, 1 or more previous lines, including lenalidomide and a PI

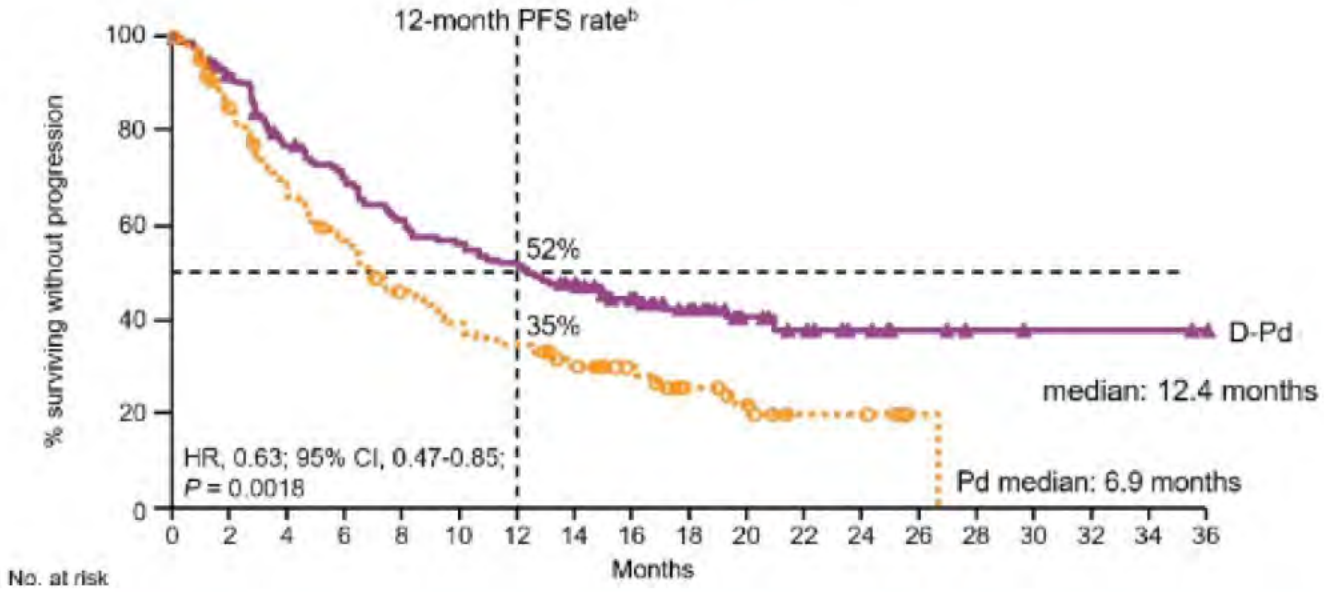
In previous phase 1-2 study: safe and effective regimen DARA-iv + pom-dex

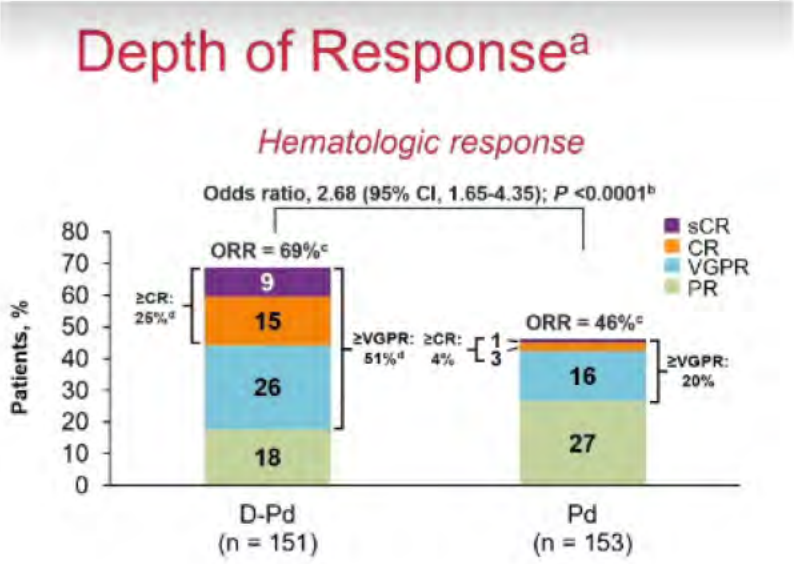
Number of patients: A: 151 vs B: 153

Dimopoulos, paper ID 412

Relapsed/refractory MM (RRMM) - early relapse

Based on IMID, PI, anti-CD38





DARA SC plus Pd is an effective and convenient treatment for patients with RRMM who received ≥1 prior therapy, including lenalidomide and a PI

Dimopoulos, paper ID 412

Relapsed/refractory MM (RRMM) - early relapse
Based on IMID, PI, anti-CD38

CMRG04 - Phase 2 study

Arm A: daratumumab + dexamethasone + cyclophosphamide + pomalidomide
vs
Arm B: daratumumab + dexamethasone + cyclophosphamide

RRMM, 1 or more previous lines, no previous daratumumab or pomalidomide
Number of patients: 61 + 59
Median prior lines: 2

Sebag paper ID 413

Relapsed/refractory MM (RRMM) - early relapse

Based on IMID, PI, anti-CD38

Median follow-up: 25.3 months

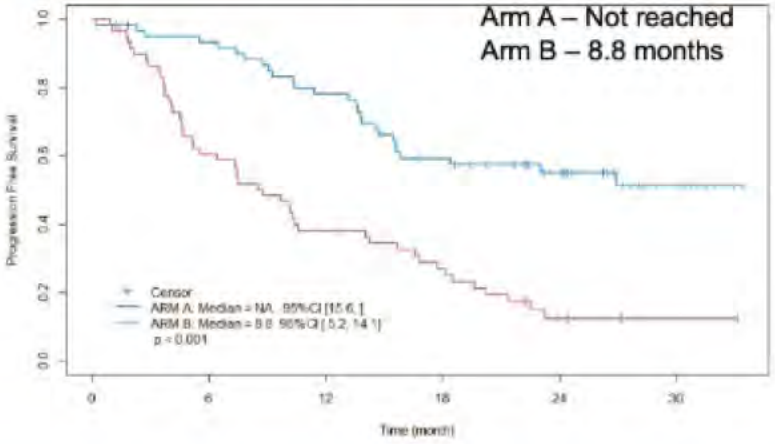
Around 40% of treatment discontinuation was because of PD

ORR 88.6 vs 50%

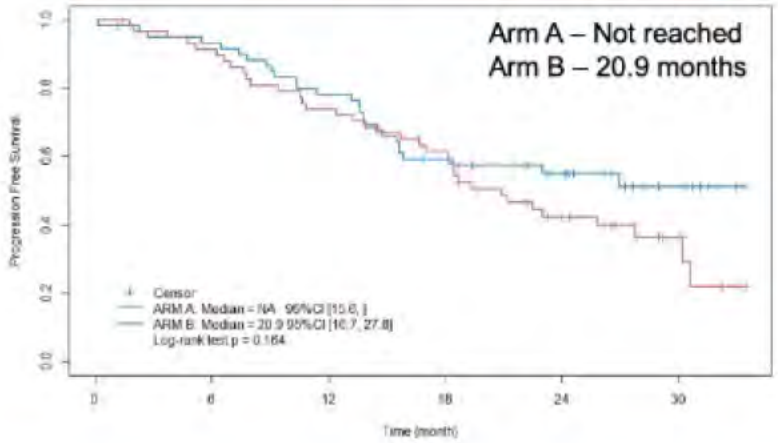
Adverse events - grade 3 or higher

- neutropenia:	85%	29%	50%
- febrile neutropenia:	13%	3%	20%
- thrombocytopenia:	8%	12%	13%
- anemia:	13%	22%	22%
- pneumonia:	21%	7%	26%

PFS Arm A vs Arm B prior to POM



PFS ARM A vs PFS of ARM B post POM



Sebag paper ID 413

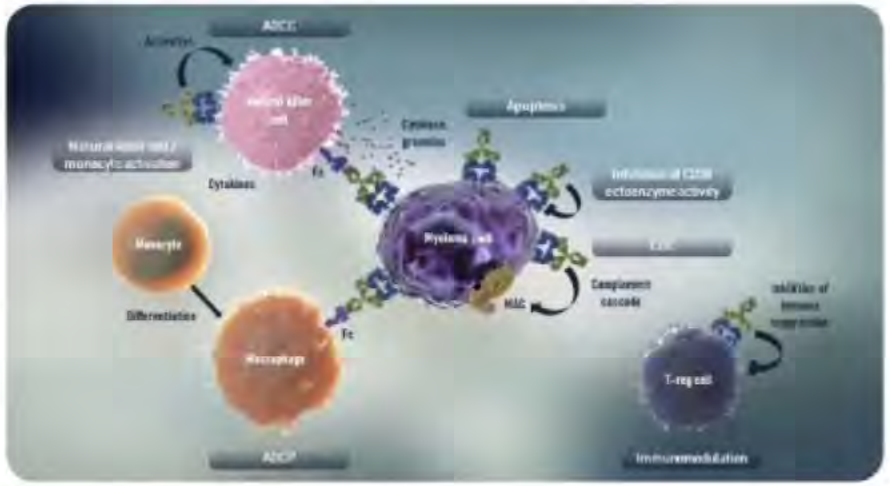
Relapsed/refractory MM (RRMM) - early relapse

Based on IMID, PI, anti-CD38

IKEMA study - depth of response and kinetics

Isatuximab + carfilzomib + dexamethasone	N=179
vs	
Carfilzomib + dexamethasone	N=123

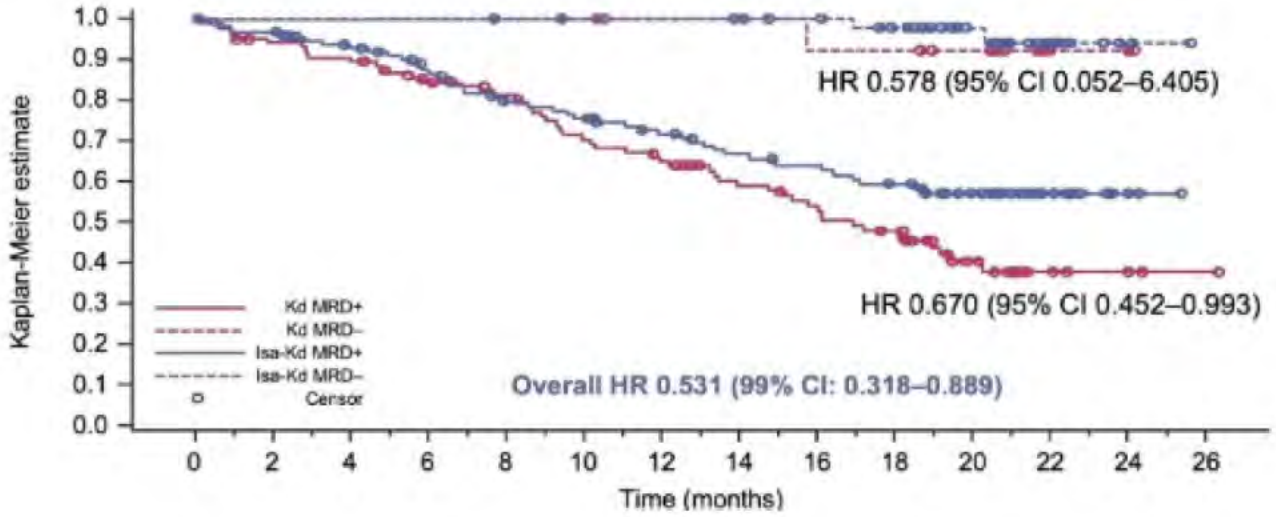
Median prior lines: 1-2

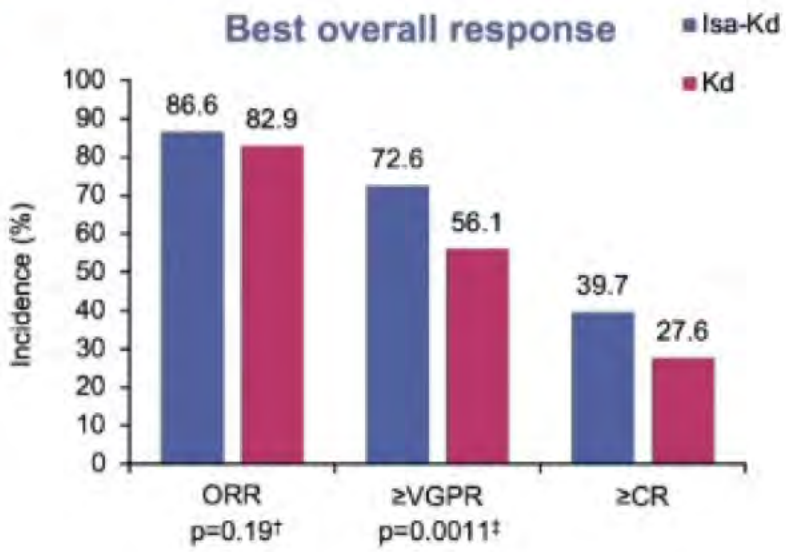


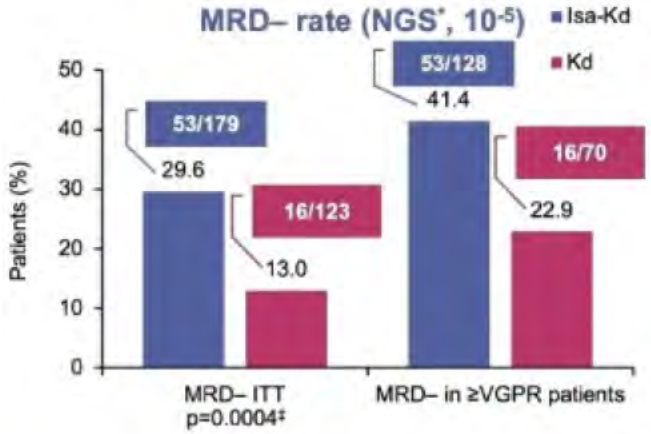
Martin paper ID 414

Relapsed/refractory MM (RRMM) - early

Based on IMID, PI, anti-CD38







Longer response and deeper response for Isa-Car-Dex!

Martin paper ID 414

Content

Introduction

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- Transplant eligible / role of autologous stem cell transplant
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Relapsed/refractory MM (RRMM) - early relapse
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Relapsed/refractory MM – late relapse
- **Bispecifics**
- CAR-T
- Antibody drug conjugates

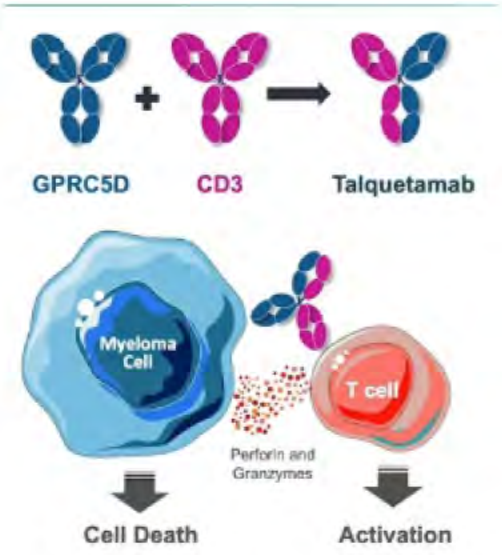
AL amyloidosis

Take home messages

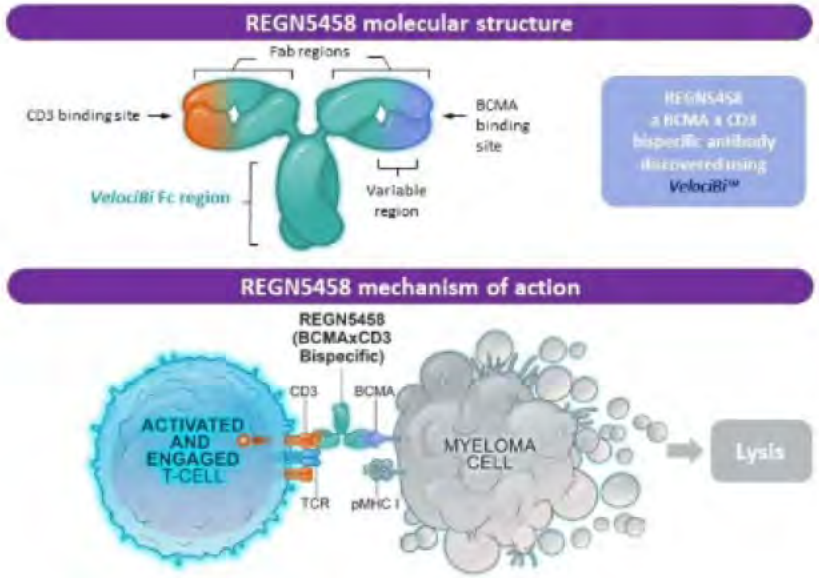
Relapse/refractory MM (RRMM)
Bispecific

Mechanisms of action:

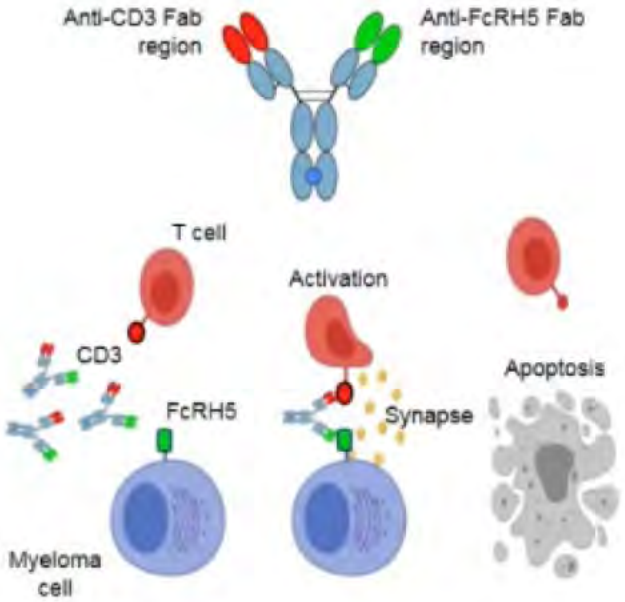
GPRC5D



BCMA



FcRH5



Left to right: Chari, paper ID 290; Madduri, paper ID 291; Cohen, paper ID 292

Relapsed/refractory MM (RRMM)

Bispecific

Paper ID	Name	Study drug	Target	Phase	Form	Number of patients	median lines prior therapy	CRS grade 3+	Evaluable patients	ORR	VGPR or better	median duration of response	other
290	Chari	Talquetamab	GPRC5D	1&2	IV and SC	157/19	6	5/0%	13	69%	39%	RP2D: 0/17 PD bij mFU 3.7m	Q1W or Q2W
291	Madduri	REGN5458	BCMA	1	IV	49	5	0%	8 at DL6	62.5%	62.5%	6m in all responders, 74% is still ongoing treatment	Q1W, later Q2W. Improvement in HRQoL
292	Cohen	Cevostamab	FcRH5	1	IV	53	6	2%	34, >3.6/20mg	53%	32%	8 pt mDOR >6m	Q3W
293	Rodriquez	TNB-383B	BCMA	1	IV	58	6	0%	15, >40mg	80%	73.3%	81% still ongoing (22/27)	Longer half life: Q3W
180	Garfall	Teclistamab	BCMA	1	IV and SC	84/65	6	0%	22 (SC)	73%	55%	15/16 are still responding at 3.9m	Q1W
181	Harrison	AMG-701	BCMA	1	IV	85	6	9%	6	83	50	17/21 ongoing at FU of 6m	Q1W

Safety		Grade 3 or higher - hematologic			Non hematologic	
Paper ID	Name	Neutropenia	Thrombopenia	Anemia	Infections	
290	Chari	42%	5%	0%	0%	
291	Madduri	14%	6%	22%	18%	
292	Cohen	15%	25%	19%	-	
293	Rodriquez	16%	14%	17%	14%	
180	Garfall	33%	12%	21%	27%	at recommened RP2D
181	Harrison	25%	21%	42%	17%	all grade AE's

Future perspective: more phase 2 and 3 studies

References in table

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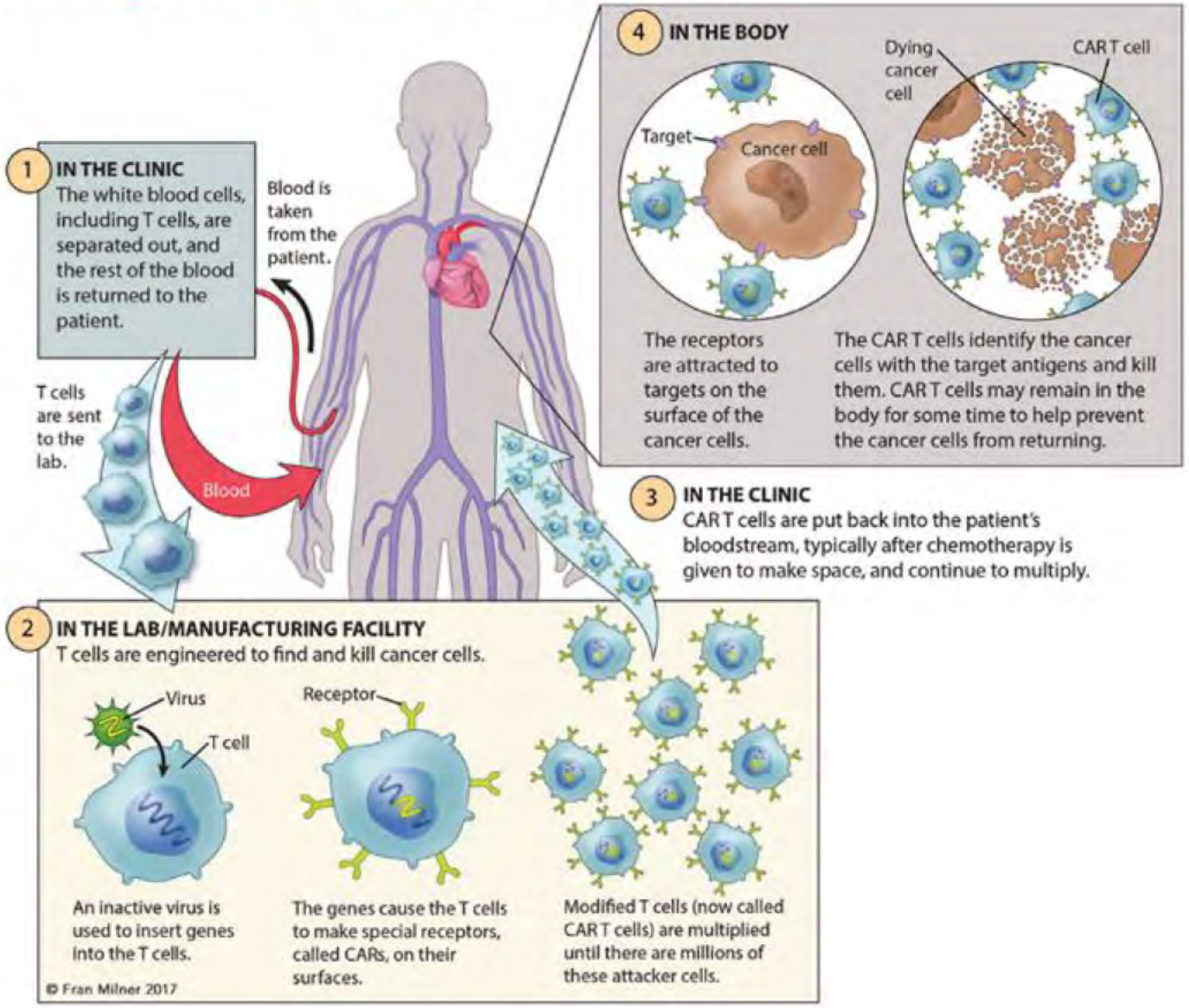
- Antibody drug conjugates

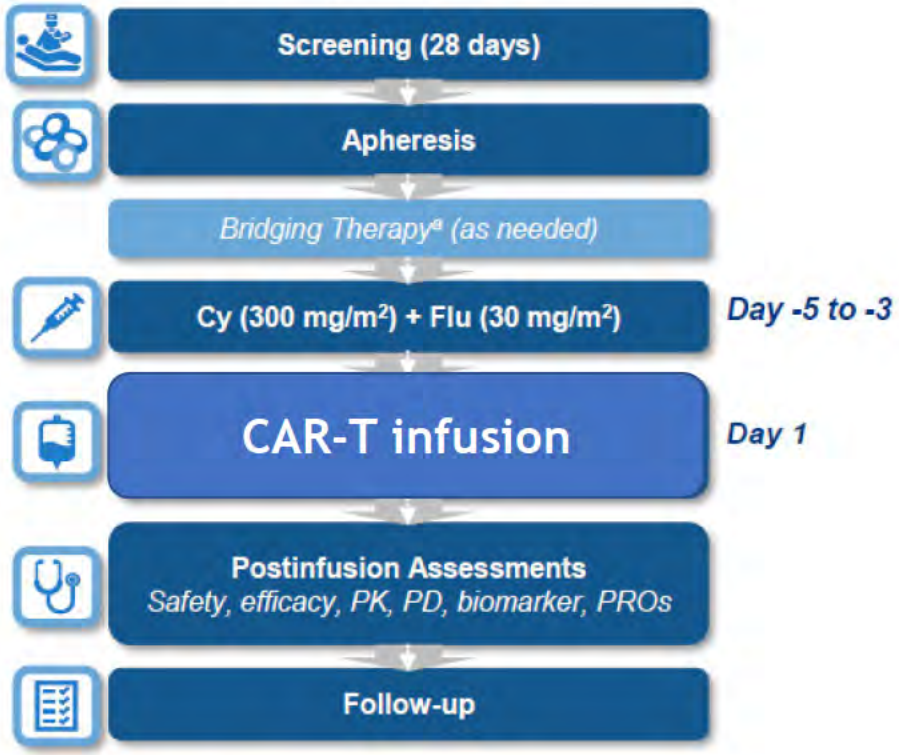
AL amyloidosis

Take home messages

Autologous CAR T-Cell Therapy Process



Study scheme



Key Eligibility Criteria

- Progressive MM per IMWG criteria
- ECOG PS ≤1
- Measurable disease
- ≥3 prior therapies or double refractory
- Prior PI, IMiD, anti-CD38 therapy

From: Leukemia & lymphoma society (https://www.lls.org/treatment/types-of-treatment/immunotherapy/chimeric-antigen-receptor-car-t-cell-therapy)
Lin et al POSTER Paper ID 3240

Relapsed/refractory MM (RRMM)

CAR-T

DOR: duration of response; no: number; ORR: overall response rate; pts: patients; RRMM: relapsed refractory multiple myeloma; VGPR: very good partial response

Study	Name	Study drug	Target	Phase	No pts	Prior lines	CRS grade ≥3	Neuro tox ≥3	ORR (%)	≥VGPR (%)	PFS (mo)	AE grade ≥3	Other
KarMMa[1]	Raje	Ide-cel (bb2121)	BCMA	1	128	6 (3-16)	5		73	53	>8.8	99	
CRB-401[2]	Lin	Ide-cel (bb2121)	BCMA	1	62	6 (3-18)	7	2	76		8.8	98 Infect 23%	
CARTITUDE-1[3,4]	Madduri	Cilta-cel	BCMA (2x)	1b/2	97	6 (3-18)	5	9	97	93	77% 12 mo	Hem: 99% Infect 20%	Triple R 88% penta 42%
GC012F[5]	Jiang	GC012F	BCMA and CD19	1	16	5 (2-9)	13	-	100% (n=6)				Penta E 63%.
C-CAR088[6]	Lu	C-CAR088	BCMA	1	23	4 (2-12)	4	-	96	92	56% 6 mo	Infect 26%	
CT053[7]	Hao	CT053	BCMA	1		5 (2-11)	-	4	88		19	Hem:100% Infect 25%	
LUMMICAR[8]	Kumar	CT053	BCMA	1b/2	20	5 (3-11)	-	few	94			Hem:100% Infect 10%	Penta R 50%
PRIME[9]	Castello	P-BCMA-101 (Piggybac)	BCMA	1(/2)	55		-	4	44-75				Prior CAR-T allowed
UNIVERSAL[10]	Mailankody	ALLO-715 (allogeneic)	BCMA	1	26		-		To 60				Of the shelf
CRB-402[11]	Alsina	CRB-402 (bb21217)	BCMA (+PI3Ki)	1	69	6 (3-17)	1	4	68-84			Infect 26%	Triple R 67%

1. Raje et al. Abstract #3234
2. Lin et al. ORAL #131
3. Madduri et al. ORAL #177
4. Lin et al. Ciltacabtagene autoleucel. POSTER #324
5. Jiang et al. ORAL #178
6. Lu et al. ORAL # 182
7. Hao et al. ORAL #132
8. Kumar et al. ORAL #133
9. Castello et al. ORAL #134
10. Mailankody et al. ORAL #129
11. Alsina et al. ORAL #130

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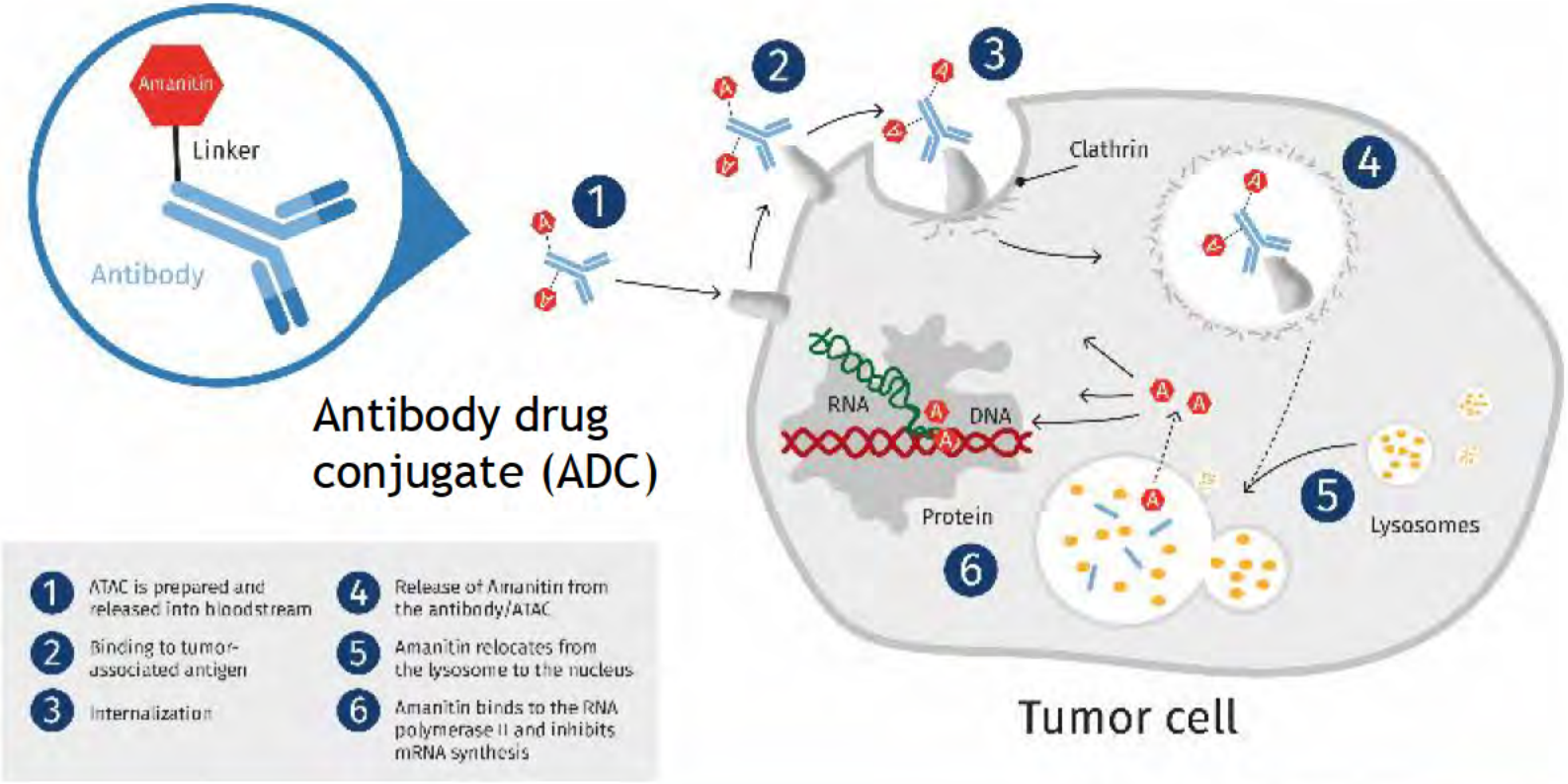
AL amyloidosis

Take home messages

Relapsed/refractory MM (RRMM)

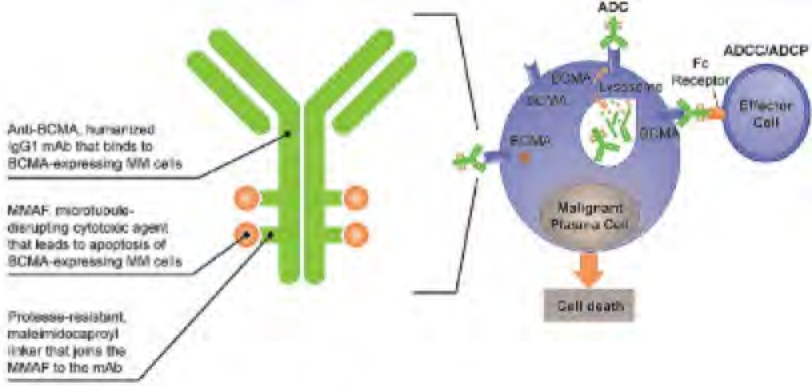
Antibody drug conjugates



From: Heidelberg-pharma.com (https://heidelberg-pharma.com/en/research-and-development/adc-technology)

Relapsed/refractory MM (RRMM)

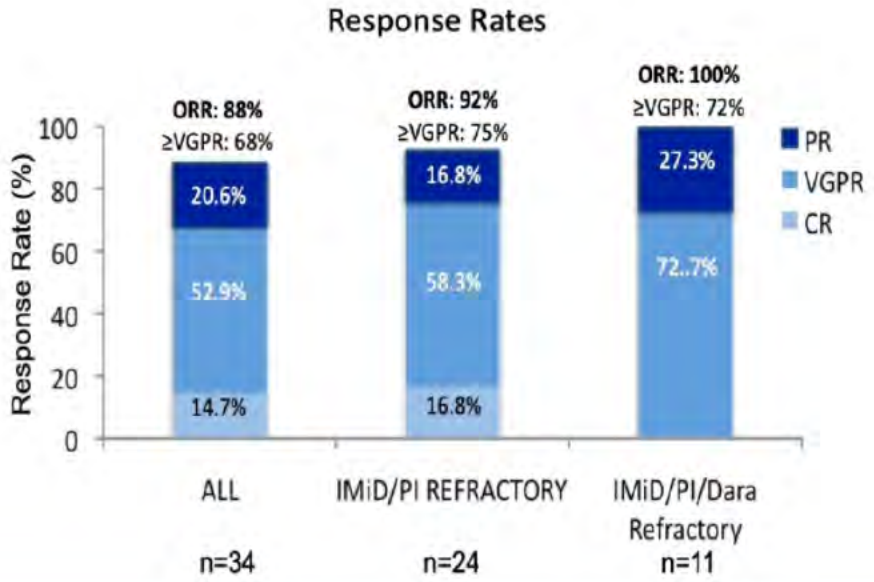
Antibody drug conjugates



Belantamab-mafodotin (BELAMAF) - added to pomalidomide-dexamethasone

Phase I ALGONQUIN study (n=37)

Prior lines 3 (1-5)



TEAE	Any Grade	≥ Grade 3
Keratopathy	28 (75.7%)	19 (51.4%)
Neutropenia	21 (56.8%)	15 (40.5%)
Thrombocytopenia	18 (48.6%)	12 (32.4%)
Decreased visual acuity	17 (45.9%)	6 (16.2%)
Fatigue	15 (40.5%)	4 (10.8%)
Fever	13 (35.1%)	1 (2.7%)
Cataract	13 (35.1%)	1 (2.7%)
Constipation	12 (32.4%)	0
Diarrhea	11 (29.7%)	0
Infusion related reaction	11 (29.7%)	2 (5.4%)

Trudel et al. ORAL Paper ID 725

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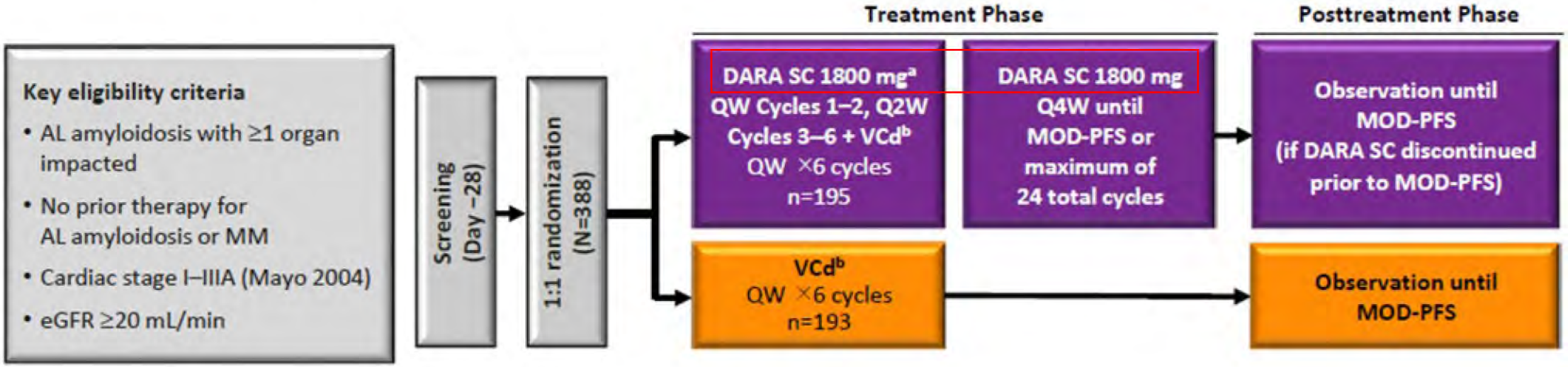
AL amyloidosis

Take home messages

AL amyloidosis
ANDROMEDA trial



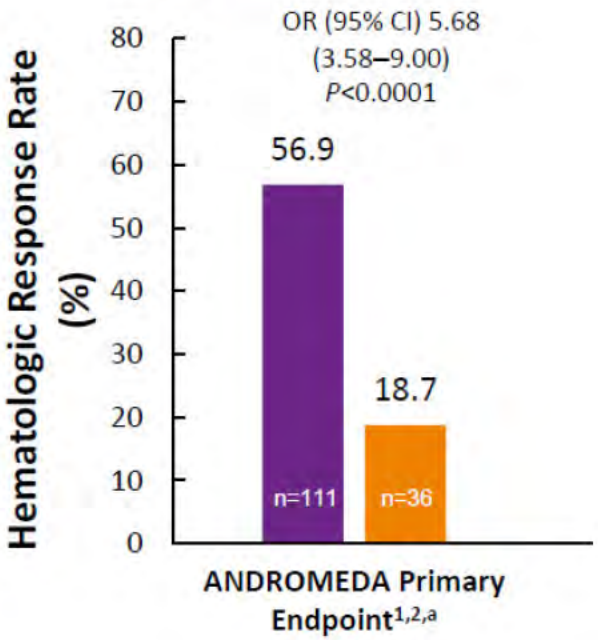
Dara: daratumumab; MOD-PFS: major organ deterioration-progression free survival; QW: weekly ; Q4W: once per 4 weeks; VCD: bortezomib-cyclophosphamide-dexamethasone

ANDROMEDA is a randomized, open-label, active-controlled, phase 3 study of DARA-VCd versus VCd alone in patients with newly diagnosed AL amyloidosis

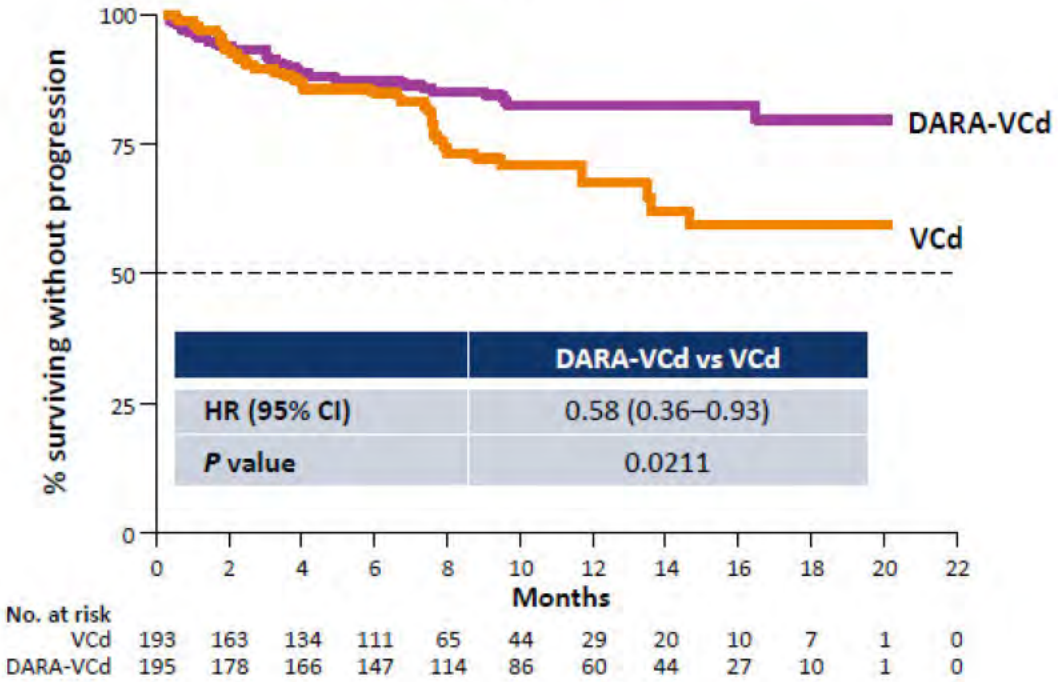
Comenzo et al. ORAL Paper ID 552
Minnema et al. Poster Paper ID 1392

AL amyloidosis
ANDROMEDA trial

Response



Major organ deterioration PFS



Treatment with DARA-VCd substantially delayed major organ deterioration, hematologic progression, or death

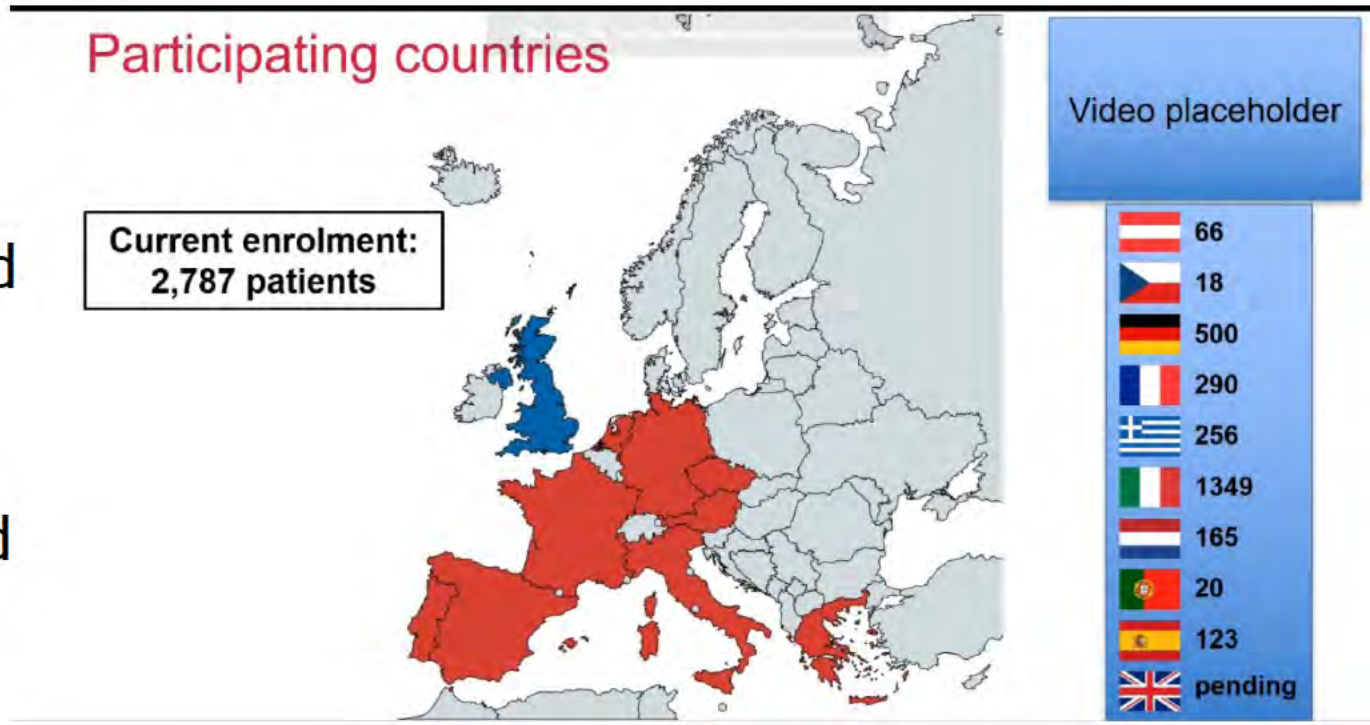
Comenzo et al. ORAL Paper ID 552
Minnema et al. Poster Paper ID 1392

AL amyloidosis
Real-world outcomes

EMN23: Collaboration between European centers to assess real-world

Goals:

- Describe the disease burden and treatment of AL-amyloidosis in real-world



Kastritis et al. ORAL paper ID 553

Take home messages

Myeloma field is evolving rapidly

Addition of daratumumab in first line in near future?

Still a role for autologous stem cell transplant

New combinations with anti-CD38, IMID and/or PI for early relapsed MM

Development of new promising agents
- CAR-T, bispecifics and many more…