Highlights from IMW 2019

Mieloma e neoplasie plasmacellulari ad alto rischio

Strategie terapeutiche adattate al rischio

Dr. Vittorio Montefusco

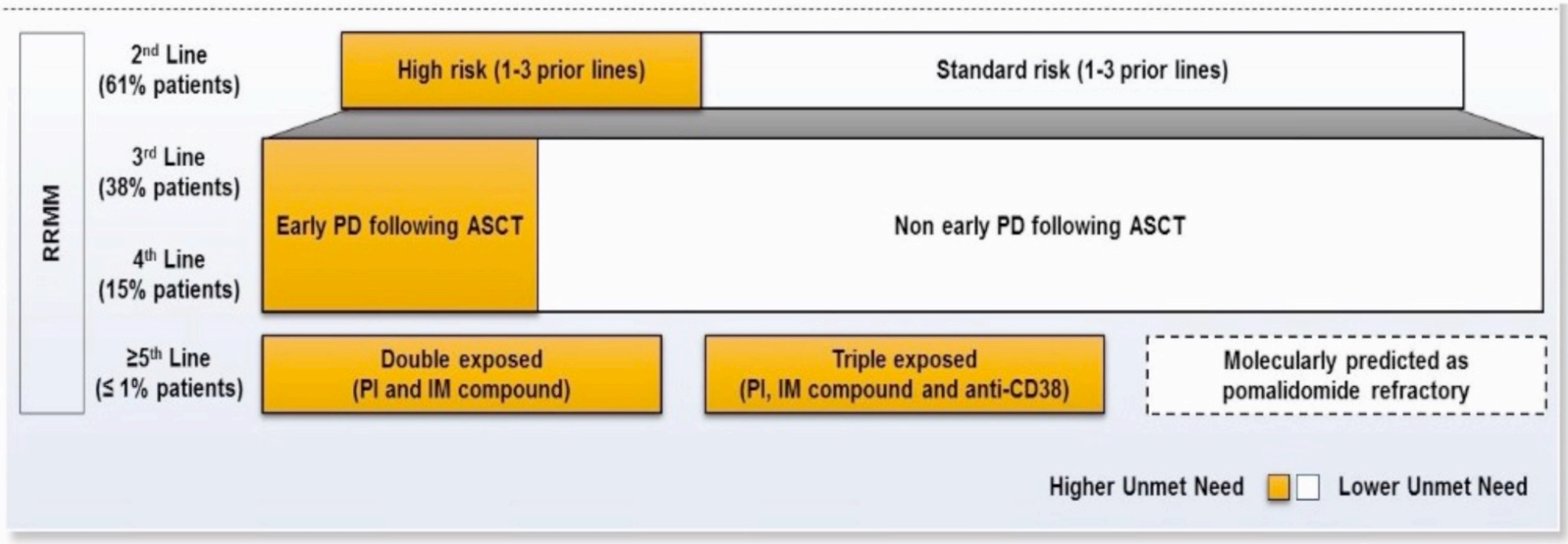
Fondazione IRCCS
Istituto Nazionale
dei Tumori

DISCLOSURES

Honoraria and travel grants from:

- **Celgene**
- **Janssen**
- **Amgen**
- **Bristol-Myers Squibb**
- **Takeda**

Patient Populations with High Unmet Medical Need in the RR setting



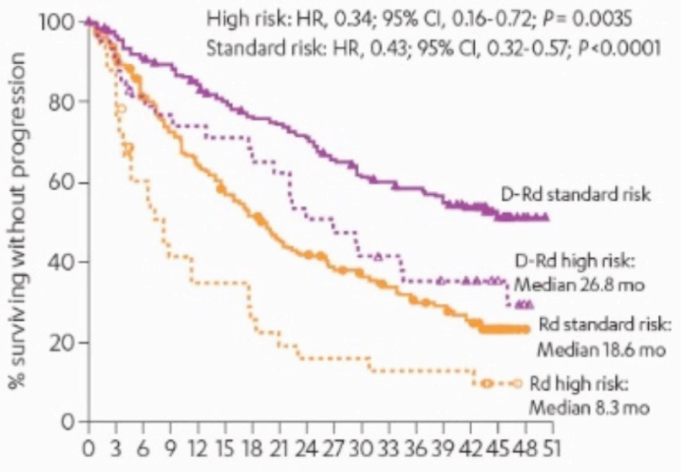
Dimoupolos, IMW 2019

High Risk Disease Remains an unmet Need in RRMM

POLLUX: Results based on Cytogenetic Risk

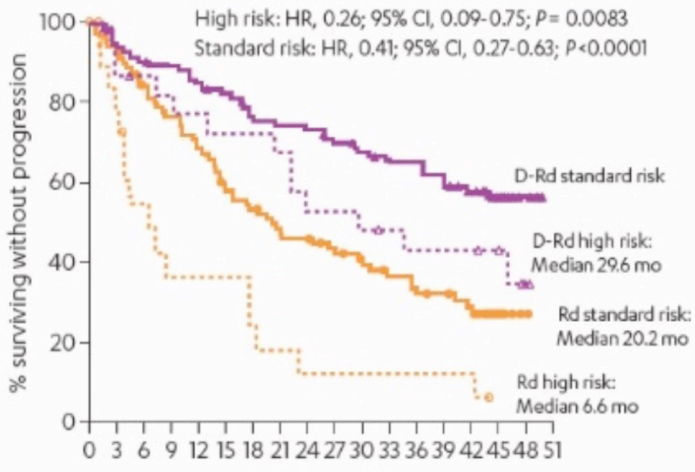
- Median follow-up: 44.3 months (ITT population)

ITT/biomarker evaluable



No. at risk																		
Rd standard risk	176	157	135	120	106	94	84	72	67	58	54	49	42	40	33	14	1	0
D-Rd standard risk	193	180	171	165	157	146	137	133	128	117	109	106	102	96	85	38	5	0
Rd high risk	35	28	19	13	11	11	8	6	5	5	5	4	4	4	4	1	0	0
D-Rd high risk	35	31	27	26	25	24	23	21	17	16	14	13	11	10	9	6	1	0

1 prior line of therapy



No. at risk																		
Rd standard risk	90	84	73	66	59	49	45	39	38	32	28	25	22	21	17	8	1	0
D-Rd standard risk	96	89	85	83	79	75	69	67	66	62	59	57	56	52	44	21	4	0
Rd high risk	20	14	9	6	6	6	4	3	2	2	2	2	2	2	2	0	0	0
D-Rd high risk	22	19	18	17	16	15	15	14	11	11	10	9	8	8	8	5	1	0

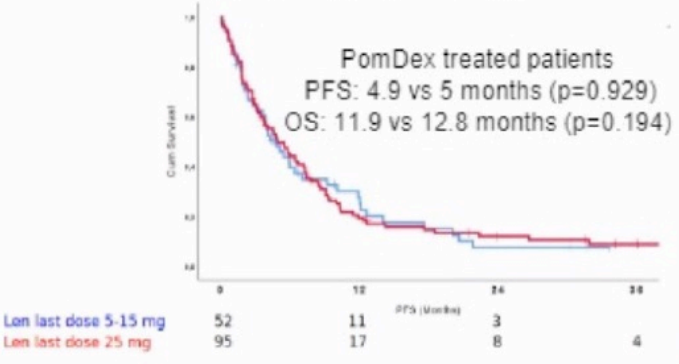
Kaufman JL, et al. ASCO 2019: Poster presentation (8038); EHA 2019: Poster presentation (PFS91)

Dimoupolos, IMW 2019

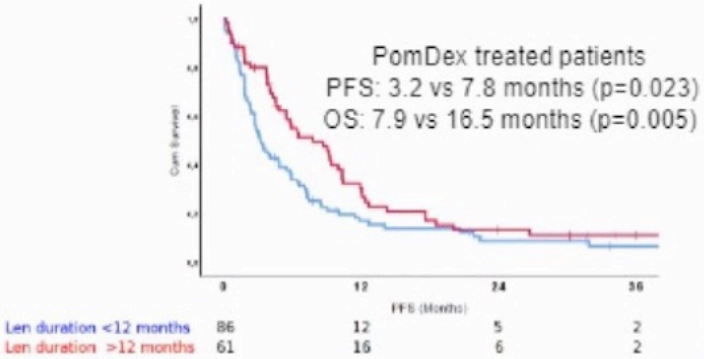
Lenalidomide Refractoriness

- How is lenalidomide resistance defined? What are the mechanisms?
- What is the impact of lenalidomide dose?
- Is the duration of prior Len exposure significant? Is it the same if exposed for long or short time to Len? Is there an IMiD-sensitive MM subtype?
- Is Lenalidomide re-treatment feasible in at least a subset of patents?
- Are newer IMiDs (CellMods) able to overcome Len-resistance more efficiently?

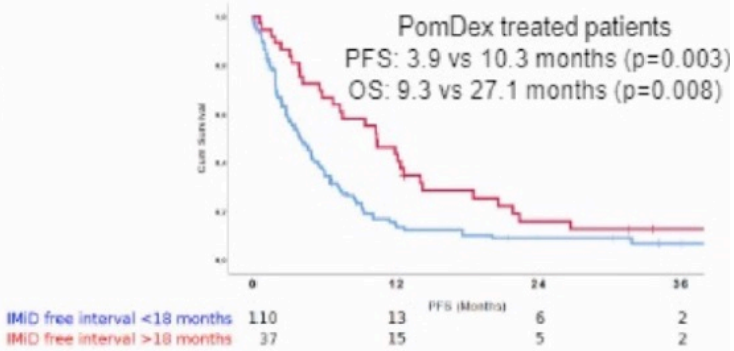
PFS according to last Len dose (5-15 mg vs 25 mg)



PFS according to Duration on Len therapy <12 vs ≥12 months



PFS according to IMiD free interval (<18 months vs ≥18 months)



Dimoupolos, IMW 2019

Kastritis E, et al. Blood Adv 2019; in press

Lenalidomide Refractoriness: An Unmet Need

Regimen	Median PFS (months)
Kd (Endeavor)	8.6
DaraVd (Castor)	7.8
PomVd (OPTIMISMM)	9.5
DaraKd (MMY1001-phase2)	25.7
DaraPomDex (MMY1001-phase 2)	10.1

Progression on Lenalidomide maintenance:

- Is resistance to maintenance lenalidomide same as resistance to lenalidomide when given in the relapsed setting or as a full therapy (as Rd or VRd?)
- What is the impact of induction therapy?
- What is the impact of lenalidomide dose?
- Can we increase to full dose and add dexa and a 3rd agent?

Dimoupolos, IMW 2019

Siegel DS et al. Haematologica 2017; abstract P333 (presented at EHA 2017);
Moreau P et al. Leukemia. 2017;31:115-22;
Richardson PG, et al. Lancet Oncol 2019;20:781-94

Efficacy of isatuximab/pomalidomide/dexamethasone in relapsed/refractory multiple myeloma: ICARIA-MM high-risk cytogenetics subgroup analysis

Simon J. Harrison[1], Paul G. Richardson[2], Adrian Alegre[3], David Simpson[4], Ming Chung Wang[5], Andrew Spencer[6], Sossana Delimpasi[7], Cyrille Hulin[8], Kazutaka Sunami[9], Thierry Facon[10], Philip Vlummens[11], Kwee Yong[12], Frank Campana[13], Marlène Inchauspé[14], Sandrine Macé[14], Marie-Laure Risse[14], Helgi van de Velde[13], Michel Attal[15]

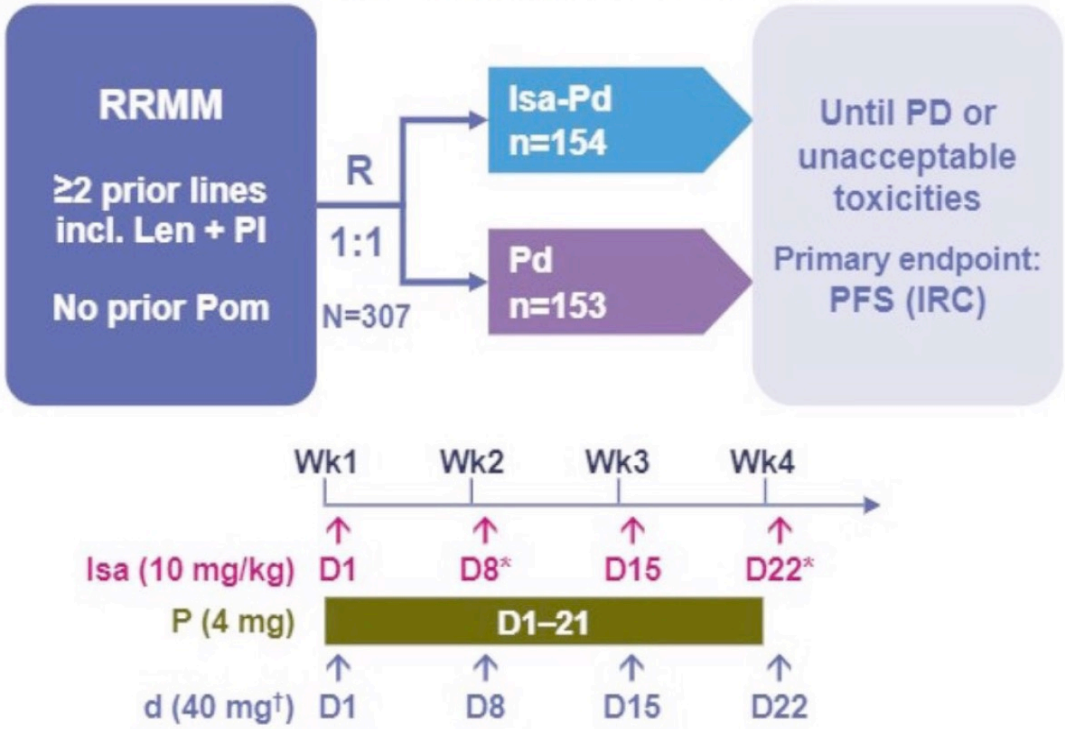
[1]Peter MacCallum Cancer Centre and Royal Melbourne Hospital, Melbourne, Victoria, Australia; [2]Medical Oncology, Dana-Farber Cancer Institute, Harvard Medica School, Boston, MA, USA; [3]University Hospital La Princesa, Madrid, Spain; [4]North Shore Hospital, Aukland, New Zealand; [5]Chang Gung Medical Foundation, Taipei, Taiwan; [6]The Alfred Hospital/MONASH University/Australian Centre for Blood Diseases, Melbourne, Victoria, Australia; [7]Evangelismos Hospital, Athens, Greece; [8]Service d'Hématologie Hôpital Haut-Lévêque CHU, Bordeaux, France; [9]Department of Hematology, National Hospital Organization Okayama Medical Center, Okayama, Japan; [10]Department of Haematology, Lille University Hospital, Lille, France; [11]Department of Haematology, Ghent University, Ghent, Belgium; [12]Department of Haematology, University College Hospital, London, UK; [13]Sanofi, Cambridge, MA, USA; [14]Sanofi R&D, Vitry-sur-Seine, France; [15]University Cancer Center of Toulouse Institut National de la Santé, Toulouse, France

Harrison, IMW 2019

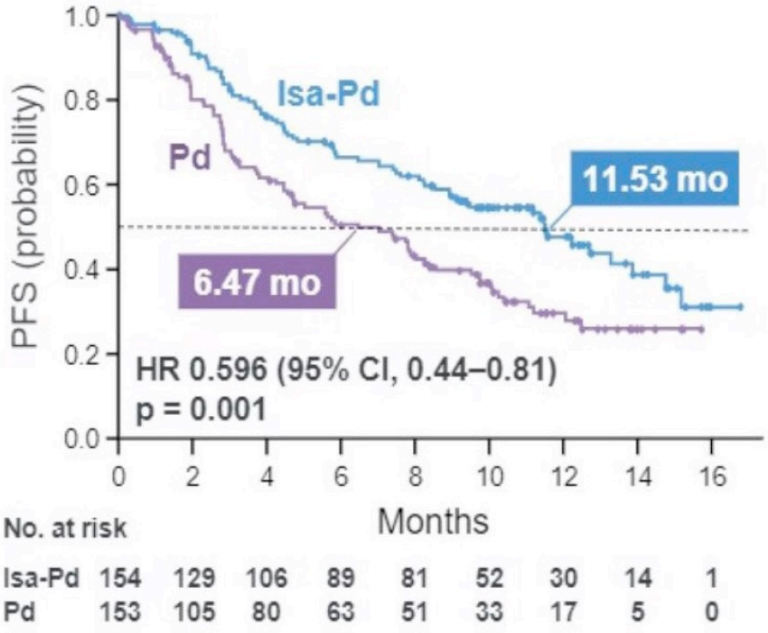
Overall study design and primary results

icaria mm

Study design (NCT02990338)[1]



PFS (IRC) in ITT population[2,‡]



Global phase 3 ICARIA-MM study: Isa-Pd significantly improved PFS vs Pd alone

*Cycle 1 only; †20 mg in patients aged ≥75 years; ‡Median follow-up duration 11.6 mo
d, dexamethasone; D, day; HR, hazard ratio; IRC, independent review committee; Isa, isatuximab; ITT, intent-to-treat; Len, lenalidomide; mo, months; (P/Pom), pomalidomide; PD, progressive disease; PFS, progression-free survival; PI, proteasome inhibitor; R, randomization; RRMM, relapsed/refractory multiple myeloma; Wk, week

Harrison, IMW 2019

1. Richardson PG, et al. Future Oncol 2018;14:1035–47;
2. Richardson PG, et al. Presented at ASCO 2019; Abstract #8004

High-risk cytogenetic subgroup analysis

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High-risk cytogenetics was prespecified as ≥1 of:

- del(17p) — 50% cut-off
- t(4;14) — 30% cut-off
- t(14;16) — 30% cut-off

Cytogenetic risk in the ITT population at baseline, n (%)	Isa-Pd (n=154)	Pd (n=153)
Standard	103 (66.9)	78 (51.0)
High	24 (15.6)	36 (23.5)
del(17p)	14 (9.1)	23 (15.0)
t(4;14)	12 (7.8)	14 (9.2)
t(14;16)	1 (0.6)	4 (2.6)
del(17p) *and* t(4;14)	3 (1.9)	4 (2.6)
del(17p) *and* t(14;16)	0	1 (0.7)
Unknown / missing	27 (17.5)	39 (25.5)

Cytogenetic testing was performed by central laboratory

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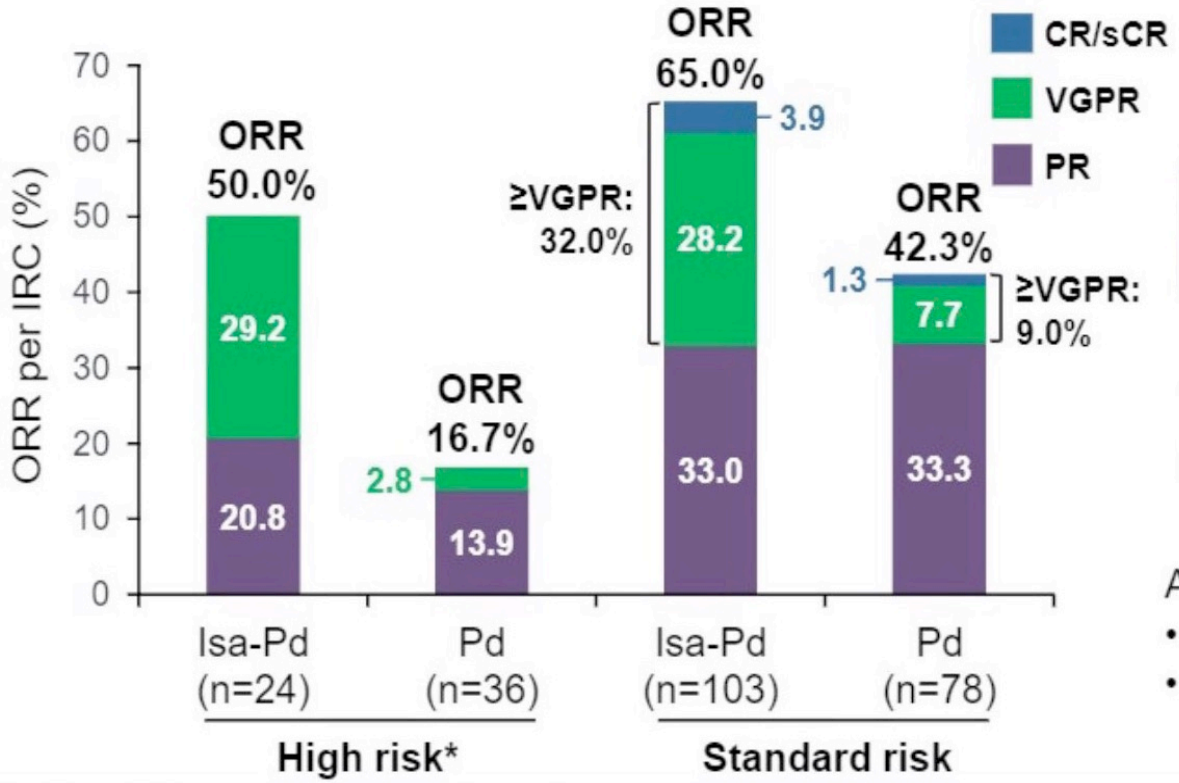
Response in cytogenetic subgroups



Isa-Pd vs Pd odds ratio (95% CI)	High risk	Standard risk
ORR	5.00 (1.33–19.79)	2.54 (1.33–4.86)
≥VGPR	14.41 (1.57–667.48)	4.78 (1.90–13.57)

Among patients with del(17p) *and* t(4;14)

- Isa-Pd (n=3), 1 VGPR
- Pd (n=4), 1 PR

ORR benefit with Isa-Pd vs Pd was maintained among patients with high-risk cytogenetics

*≥1 of del(17p), t(4;14) or t(14;16) at study entry
CI, confidence interval; CR, complete response; d, dexamethasone; IRC, independent review committee; Isa, isatuximab; ORR, overall response rate; P, pomalidomide; PR, partial response; sCR, stringent complete response; VGPR, very good partial response

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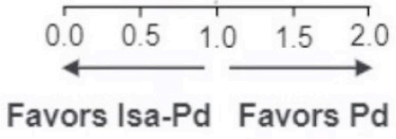
PFS in cytogenetic subgroups

Subgroup	Number of patients		Median PFS, mo		Hazard ratio (95% CI)
	Isa-Pd	Pd	Isa-Pd	Pd	
All patients	154	153	11.5	6.5	0.60 (0.44–0.81)
Cytogenetic risk					
High*	24	36	7.5	3.7	0.66 (0.33–1.28)
Standard	103	78	11.6	7.4	0.62 (0.42–0.93)
del(17p)					
Yes	14	23	9.1	7.4	0.76 (0.30–1.92)
No	118	95	11.5	5.6	0.57 (0.40–0.82)
t(4;14)					
Yes	12	14	7.5	2.8	0.49 (0.19–1.31)
No	119	101	11.6	7.0	0.58 (0.40–0.83)



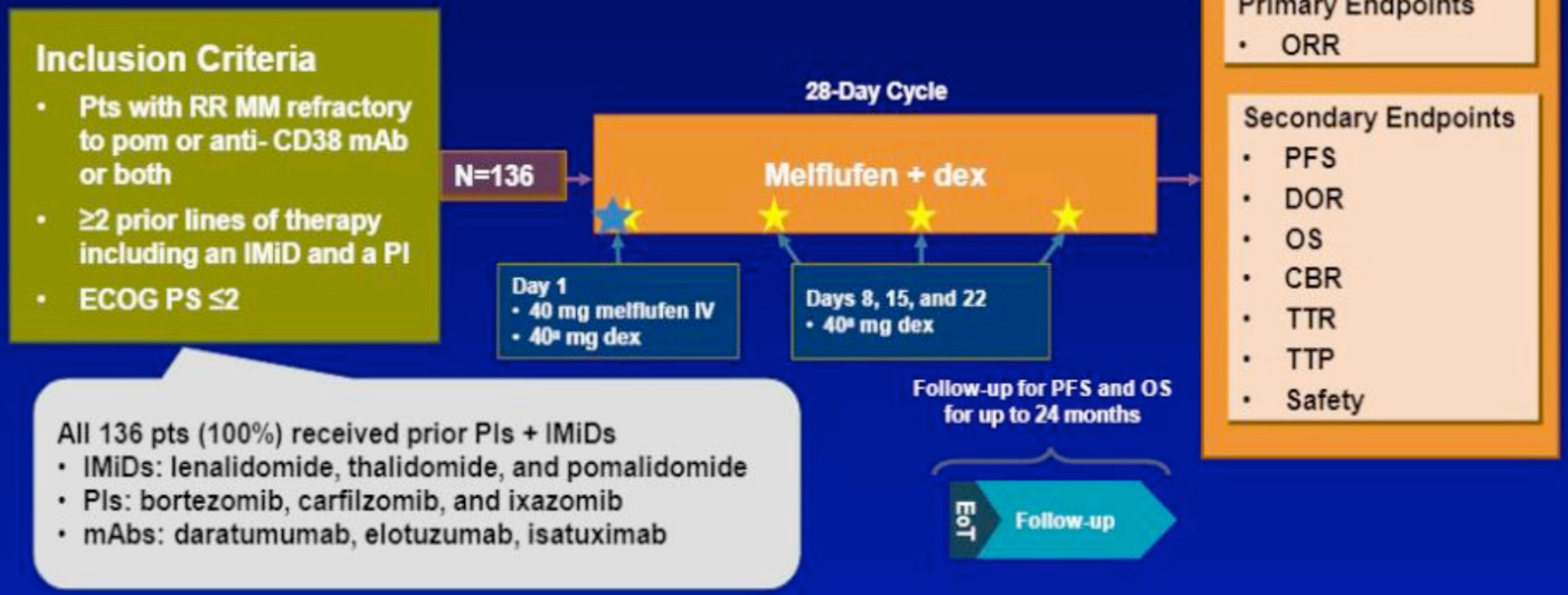
PFS benefit observed in both high- and standard-risk patients with Isa-Pd vs Pd

*≥1 of del(17p), t(4;14) or t(14;16) at study entry
CI, confidence interval; d, dexamethasone; Isa, isatuximab; mo, months; P, pomalidomide; PFS, progression-free survival

Harrison, IMW 2019

HORIZON: Study Design

Phase 2, Single-Arm, Open-Label, Multicenter Study



ClinicalTrials.gov Identified: NCT02963493.

CBR, clinical benefit rate; dara, daratumumab; dex, dexamethasone; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EoT, end of treatment; IMiD, immunomodulatory agent; IV, intravenous; mAbs, monoclonal antibodies; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; pom, pomalidomide; pts, patients; RR MM, relapsed/refractory multiple myeloma; TTP, time to progression; TTR, time to response.

[a]Pts aged >75 years received dex 20 mg.

Richardson PG, et al IMW 2019 #OAB-86

Richardson, IMW 2019

Baseline Characteristics and Prior Therapy

HORIZON

Patient Characteristics (n=130)	Non-EMD (n=86)	EMD (n=44)
Age, median (range), years	64 (35-86)	64 (43-82)
Time since diagnosis, median, years	6.6 (1.6-24.2)	5.5 (0.6-12.7)
No. of prior lines of therapy, median (range)	5 (2-10)	5 (3-12)
	%	%
Gender (male / female)	53 / 47	59 / 41
ISS stage I / II / III / unknown	42 / 29 / 23 / 6	43 / 23 / 27 / 7
ECOG PS 0 / 1 / 2 / unknown	27 / 58 / 13 / 2	18 / 64 / 16 / 2
High-risk cytogenetics[a] ≥2 high-risk abnormalities Del(17p)	57 25 19	52 10 13
Double-class (IMiD+PI) exposed / refractory	100 / 90	100 / 93
Triple-class (IMiD+PI+anti-CD38) exposed / refractory	71 / 63	93 / 91[b]
Anti-CD38 mAb exposed / refractory	72 / 72	93 / 93
Alkylator exposed / refractory	91 / 58	82 / 59
≥1 Prior ASCT ≥2 Prior ASCTs Relapsed/progressed within 1 year of ASCT	69 13 17	73 14 23
Refractory in last line of therapy	95	100

[a]High-risk cytogenetics [t(4;14), del(17/17p), t(14;16), t(14;20), nonhyperdiploidy, gain(1q) or karyotype del[13]] at study entry; data pending for 33 pts in the non-EMD group and 13 pts in the EMD group.
[b]Includes 2 PI-intolerant pts.

Richardson PG, et al IMW 2019 #OAB-86

EMD Characteristics

HORIZON

Bone-related or Soft Tissue EMD, n (%)	EMD Pts	CNS Involvement
Pts with EMD[a]	44 (100)	5 (11)
Soft tissue[b]	26 (59)	2 (5)
Bone-related[c]	18 (41)	3 (7)

CNS, central nervous system; EMD, extramedullary disease; Pt, patient.
[a]Majority of pts had multiple lesions at baseline.
[b]Includes pts with both bone-related and soft tissue EMD.
[c]Three pts had bone-related EMD with extension into CNS.

- Method of baseline assessment for known or suspected EMD was by investigator choice including PET/CT, MRI and physical examination
- 59% of pts had soft-tissue EMD (with or without additional bone-related EMD) and 41% had bone-related EMD alone
- 5 pts (11%) had CNS involvement, of which 3 pts had bone-related EMD with extension into CNS
- Majority of pts (29 of 44) had multiple sites of EMD

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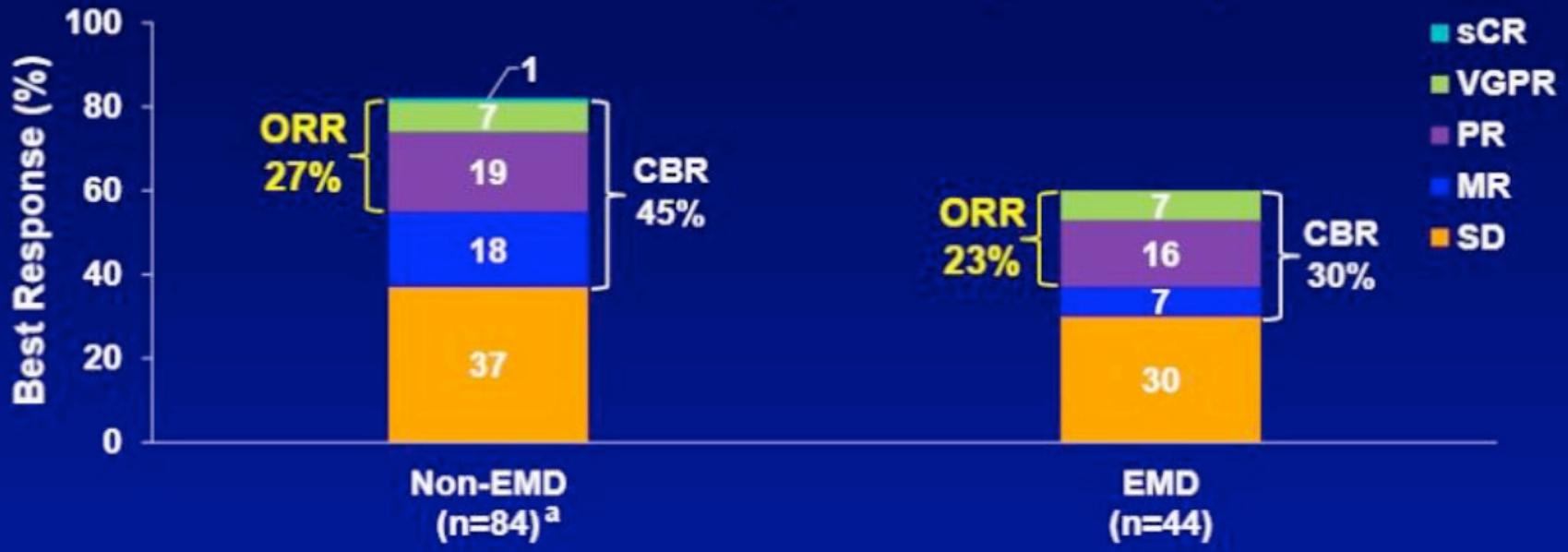
Overall Response (n=128)



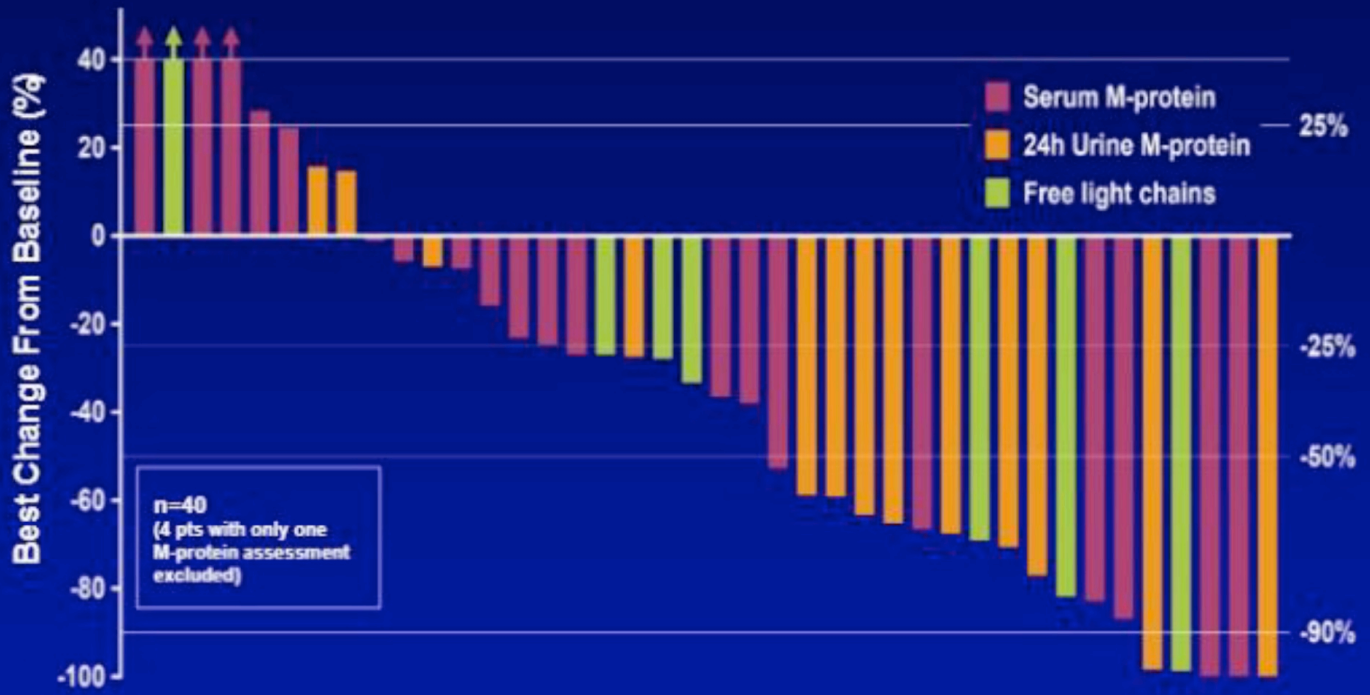
- Similar ORR in non-EMD and EMD pts, with an ORR of 27% and 23% respectively
  - Investigator-assessed response[1]
  - IRC review ongoing
- Median DOR for non-EMD pts 4.4 mos (95% CI, 3.5-11.2)
- Median DOR for EMD pts 3.4 mos (95% CI, 1.8-15.4)

[a] Two non-EMD pts with pending response information available at data cut off 30th July 2019.

1. Rajkumar SV, et al. *Blood*. 2011;117:4691-4695.

Response in EMD Pts (n=44)

HORIZON



n=44	ORR
Soft tissue n=26	19%
Bone-related n=18	28%
CNS n=5	0%

- PET/CT (including TIMC), MRI, physical exam for EMD assessment
- "Flaring" observed in EMD PET/CT imaging (reported by 2 lead sites)

Data cutoff 30 July 2019.

Richardson PG, et al IMW 2019 #OAB-86

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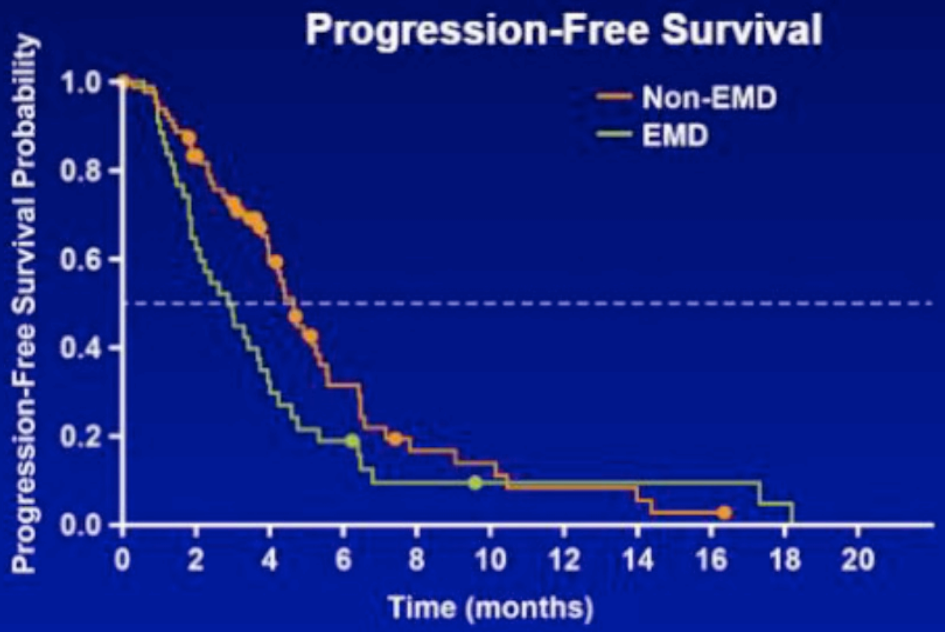
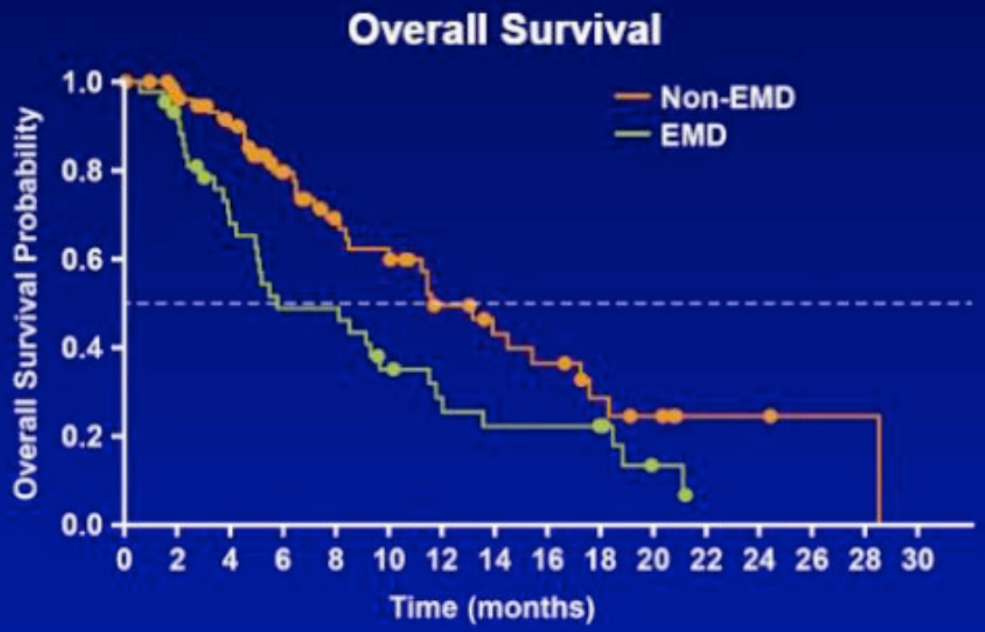
Progression-Free and Overall Survival EMD vs Non-EMD Pts

HORIZON





- Median PFS 2.9 mos (95% CI, 2.0-4.0) for pts with EMD vs. 4.6 mos (95% CI, 4.0-5.6) without EMD
- Median OS 5.8 mos (95% CI, 5.0-11.8) for pts with EMD vs. 11.6 mos (95% CI, 10.0-17.6) without EMD

Data cutoff 30 July 2019.

Richardson PG, et al IMW 2019 #OAB-86

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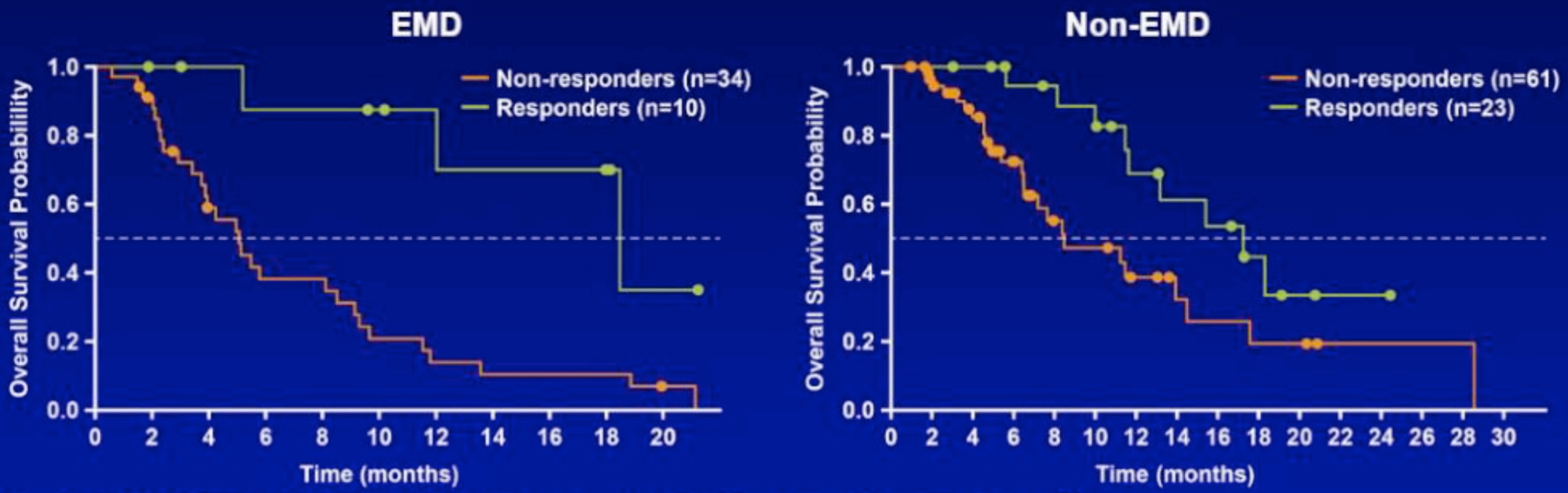
OS in EMD and Non-EMD Pts Stratified by Response

HORIZON



- Median OS in EMD responders vs. non-responders: 18.5 vs. 5.1 mos
- Median OS in Non-EMD responders vs. non-responders: 17.2 vs. 8.5 mos
  - Similar trend for PFS in responders vs. non-responders: 4.8 vs. 2.2 mos in EMD pts; 6.4 vs. 3.8 mos in non-EMD pts
- 54% of ITT pts received subsequent therapy with no significant difference in outcome between EMD vs. non-EMD pts[1]

Data cutoff 30 July 2019.

1. Gandhi UH, et al. *Blood*. 2018;132(suppl 1):Abstract 3233.

Daratumumab Plus Bortezomib, Thalidomide, and Dexamethasone (D-VTd) in Transplant-eligible Newly Diagnosed Multiple Myeloma (NDMM): Subgroup Analysis of High-risk Patients in CASSIOPEIA*

Pieter Sonneveld,[1] Michel Attal,[2] Aurore Perrot,[3] Cyrille Hulin,[4] Denis Caillot,[5] Thierry Facon,[6] Xavier Leleu,[7] Karim Belhadj,[8] Lionel Karlin,[9] Lotfi Benboubker,[10] Mark-David Levin,[11] Monique C. Minnema,[12] Matthijs Westerman,[13] Michel Delforge,[14] Sonja Zweegman,[15] Lixia Pei,[16] Carla de Boer,[17] Veronique Vanquickelberghe,[18] Tobias Kampfenkel,[17] Philippe Moreau[19]; on behalf of **IFM** and **HOVON**

[1]Erasmus MC Cancer Institute, Rotterdam, The Netherlands; [2]Institut Universitaire du Cancer de Toulouse-Oncopole, Toulouse, France; [3]Hematology Department, University Hospital, Vandoeuvre Les Nancy, France; [4]Department of Hematology, Hospital Haut Leveque, University Hospital Bordeaux, France; [5]CHU Dijon, Hôpital Du Bocage, Dijon, France; [6]University of Lille, CHU Lille, Service des Maladies du Sang, Lille, France; [7]CHU Poitiers – Hôpital la Milétrie, Poitiers, France; [8]Hematology, Hopital Henri Mondor, Creteil, France; [9]Centre Hospitalier Lyon-Sud Hematologie (HCL), Pierre – Benite Cedex, France; [10]CHU de Tours, Hôpital de Bretonneau, Tours, Cedex 9, France; [11]Albert Schweitzer Hospital, Dordrecht, The Netherlands; [12]Department of Hematology, UMC Utrecht Cancer Center, Utrecht, The Netherlands; [13]Northwest Clinics, Alkmaar, The Netherlands; [14]Universitaire Ziekenhuizen Leuven, Leuven, Belgium; [15]Amsterdam UMC, Vrije Universiteit Amsterdam, Department of Hematology, Amsterdam, The Netherlands; [16]Janssen Research & Development, LLC, Raritan, NJ, USA; [17]Janssen Research & Development, LLC, Leiden, The Netherlands; [18]Janssen Research & Development, Beerse, Belgium; [19]Hematology, University Hospital Hôtel-Dieu, Nantes, France.

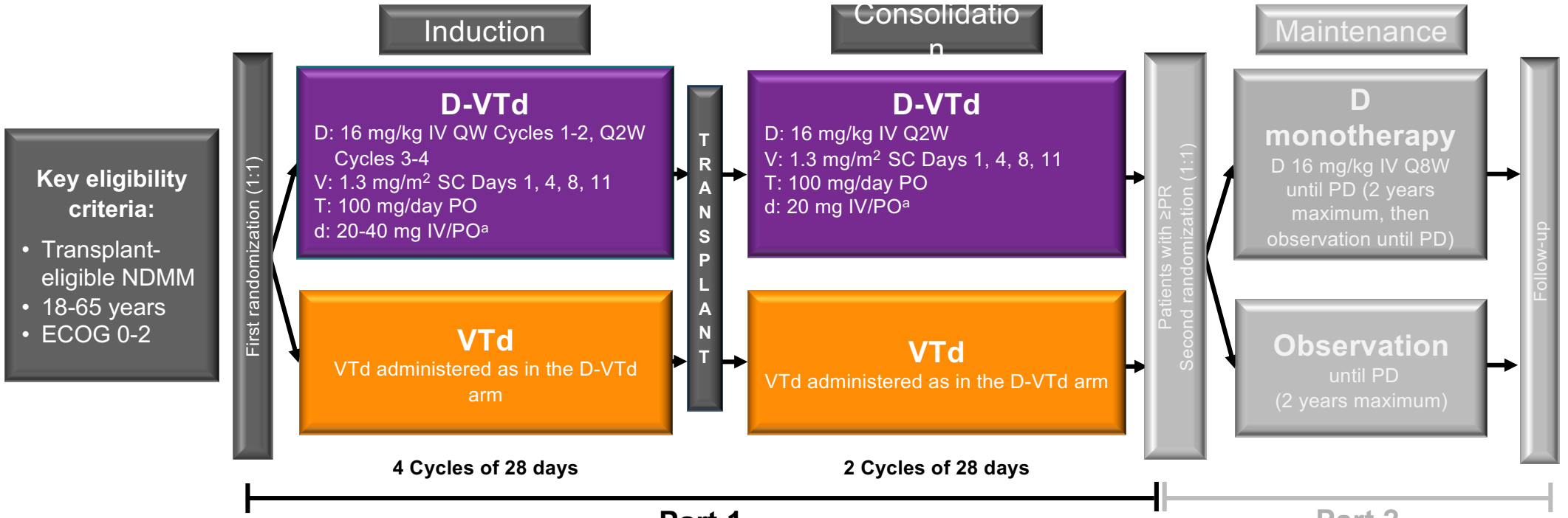
Sonneveld, IMW 2019

IFM, The Intergroupe Francophone du Myélome; HOVON, Dutch-Belgian Cooperative Trial Group for Hematology Oncology.

*ClinicalTrials.gov Identifier: NCT02541383.

CASSIOPEIA Study Design

- Phase 3 study of D-VTd versus VTd in transplant-eligible NDMM (N = 1,085), 111 sites from 9/2015 to 8/2017



Stratification factors:
- Site affiliation (IFM or HOVON)
- ISS disease stage (I, II, or III)
- Cytogenetic risk status (high or standard/unknown risk)

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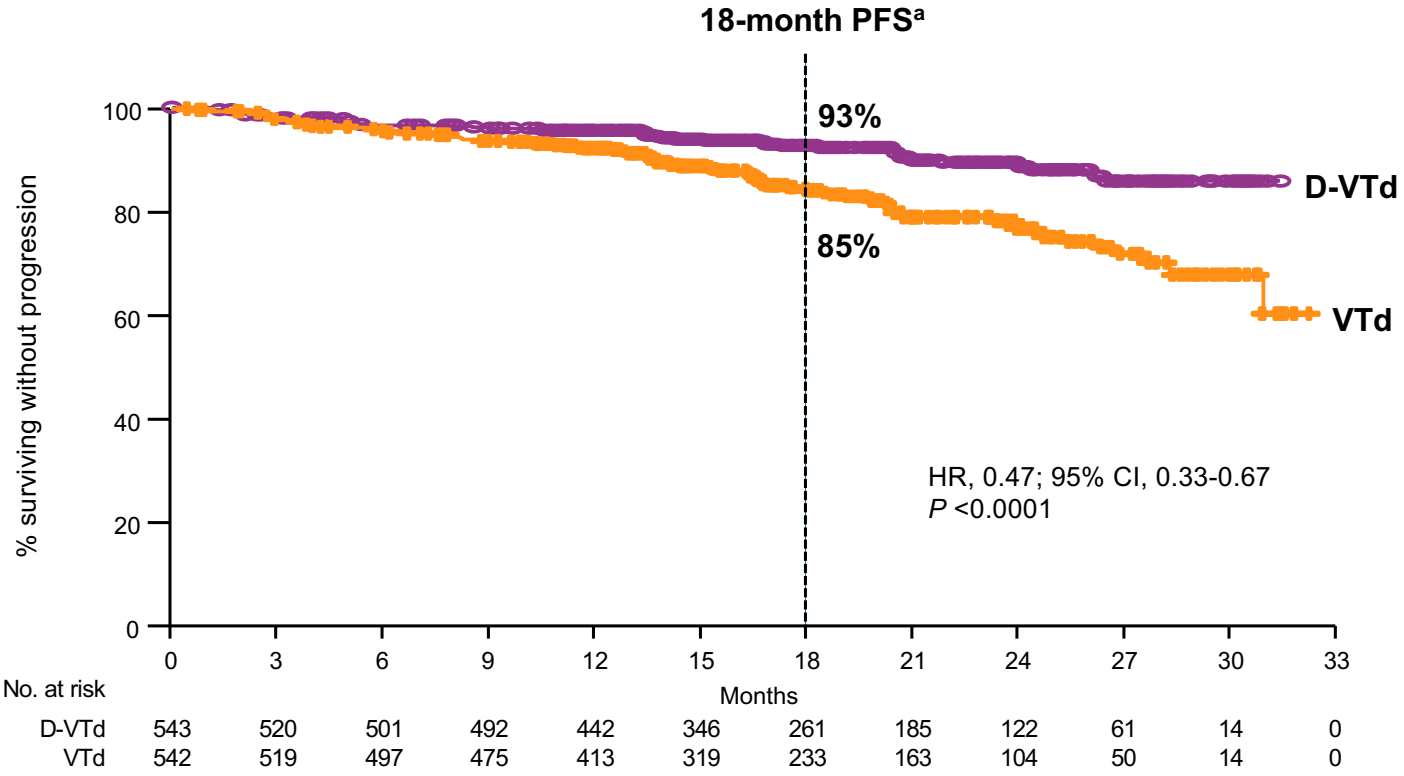
D-VTd, daratumumab/bortezomib/thalidomide/dexamethasone; VTd, bortezomib/thalidomide/dexamethasone; NDMM, newly diagnosed multiple myeloma; ECOG, Eastern Cooperative Oncology Group; IV, intravenous; QW, weekly; Q2W, every 2 weeks; SC, subcutaneous; PO, oral; PR, partial response; Q8W, every 8 weeks; PD, progressive disease; IFM, The Intergroupe Francophone du Myélome; HOVON, Dutch-Belgian Cooperative Trial Group for Hematology Oncology; ISS, International staging system.

[a]Dexamethasone 40 mg on Days 1, 2, 8, 9, 15, 16, 22, 23 of Cycles 1-2 and Days 1 & 2 of Cycles 3-4; 20 mg on Days 8, 9, 15, 16 of Cycles 3-4; 20 mg on Days 1, 2, 8, 9, 15, 16 of Cycles 5-6.

Efficacy Results: ITT Population

- Median (range) follow-up: 18.8 (0.0-32.2) months



53% reduction in the risk of progression or death with D-VTd

ITT, intent-to-treat; ORR, overall response rate; VGPR, very good partial response; HR, hazard ratio; CI, confidence interval.
[a]Kaplan-Meier estimate.

Sonneveld, IMW 2019

Baseline Demographic and Clinical Characteristics (ITT)

	D-VTd (n = 543)	VTd (n = 542)
Age		
Median (range), yrs	59 (22-65)	58 (26-65)
Male, n (%)	316 (58)	319 (59)
ECOG status,[a] n (%)		
0	265 (49)	257 (47)
1	225 (41)	230 (42)
2	53 (10)	55 (10)
Type of measurable disease,[b] n (%)		
IgG	331 (61)	314 (58)
IgA	80 (15)	99 (18)

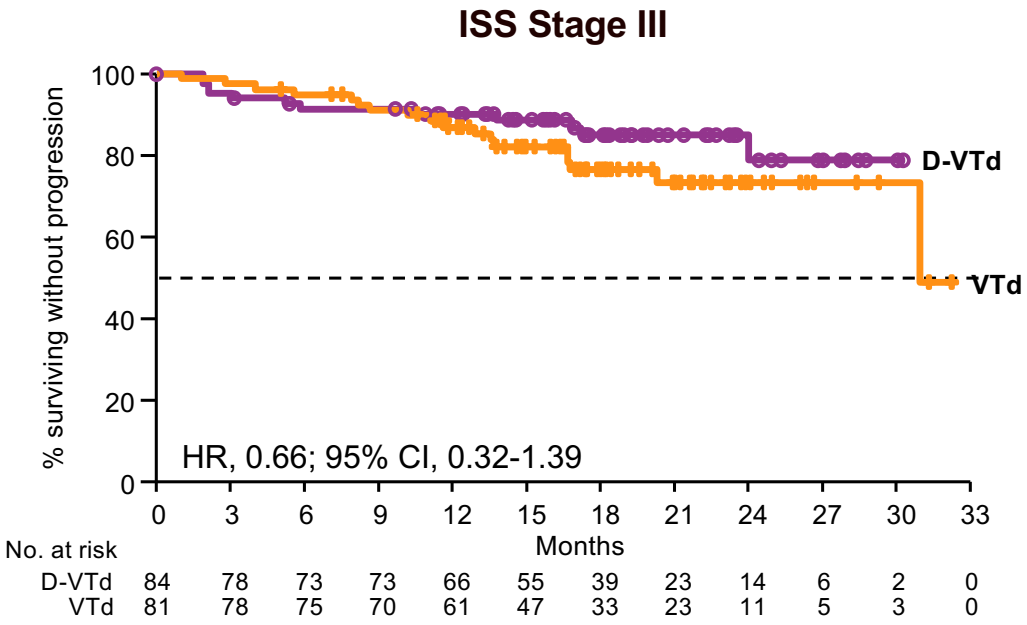
	D-VTd (n = 543)	VTd (n = 542)
ISS stage,[c] n (%)		
I	204 (38)	228 (42)
II	255 (47)	233 (43)
III	84 (16)	81 (15)
Cytogenetic profile[d]		
N	542	540
Standard risk, n (%)	460 (85)	454 (84)
High risk (del17p or t[4;14]), n (%)	82 (15)	86 (16)

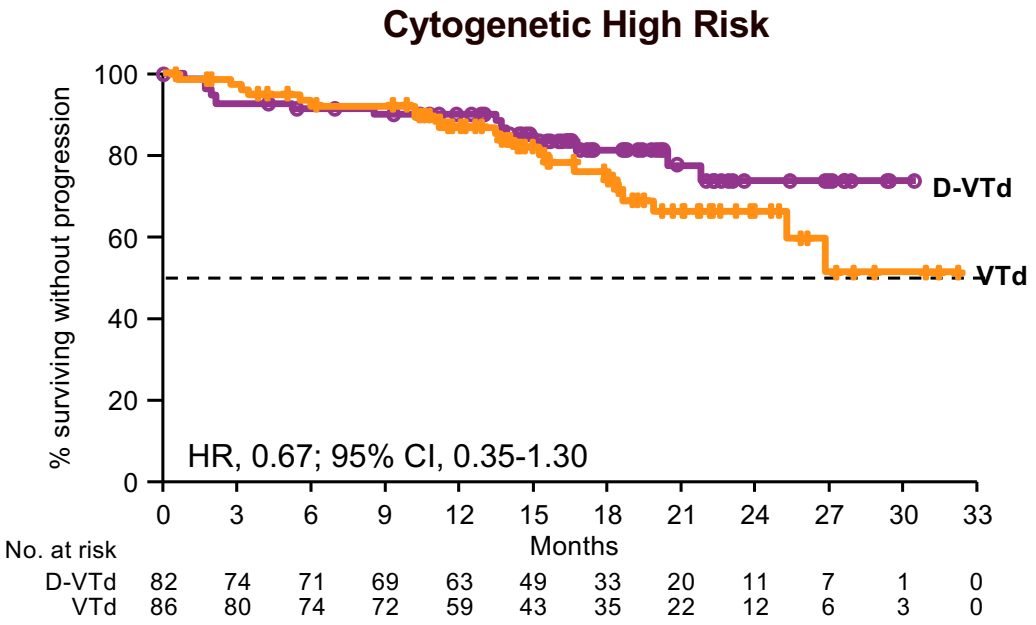
Treatment arms were well balanced

[a]ECOG performance status is scored on a scale from 0 to 5, with 0 indicating no symptoms and higher scores indicating increasing disability. [b]Includes patients without measurable disease in serum and urine.
[c]Based on the combination of serum β_2-microglobulin and albumin. [d]Based on fluorescence in situ hybridization; high risk was defined as the presence of del17p or t(4;14), as centrally confirmed during screening.
Note: Percentages may not add to 100% due to rounding.

PFS in High-risk Subgroups

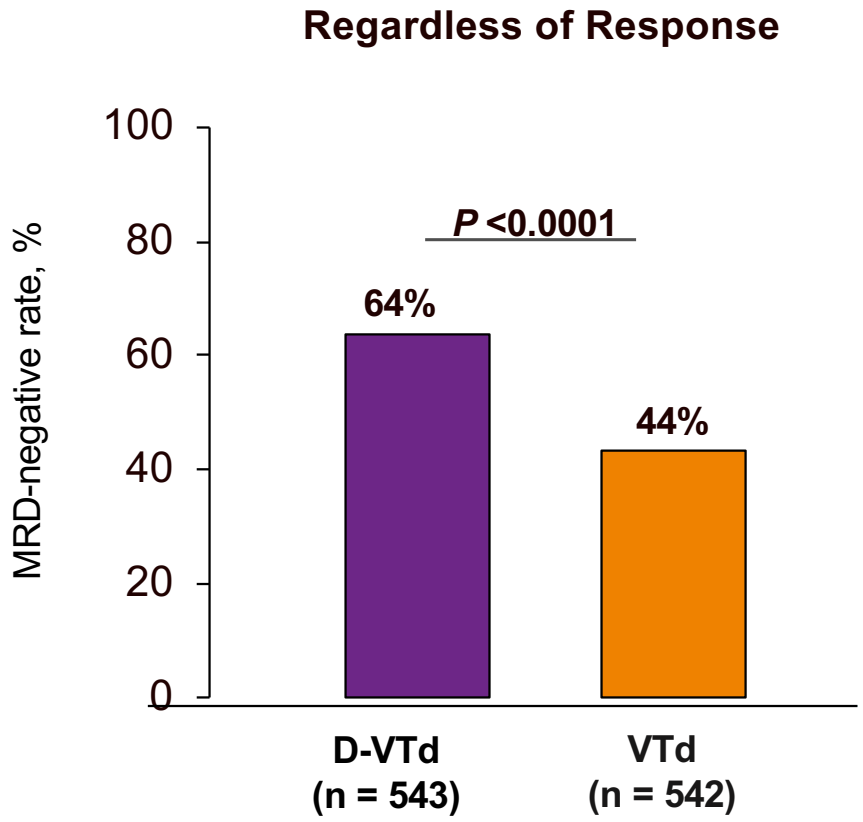
- Median (range) follow-up: 18.8 (0.0-32.2) months





D-VTd reduced the risk of progression or death in high-risk subgroups

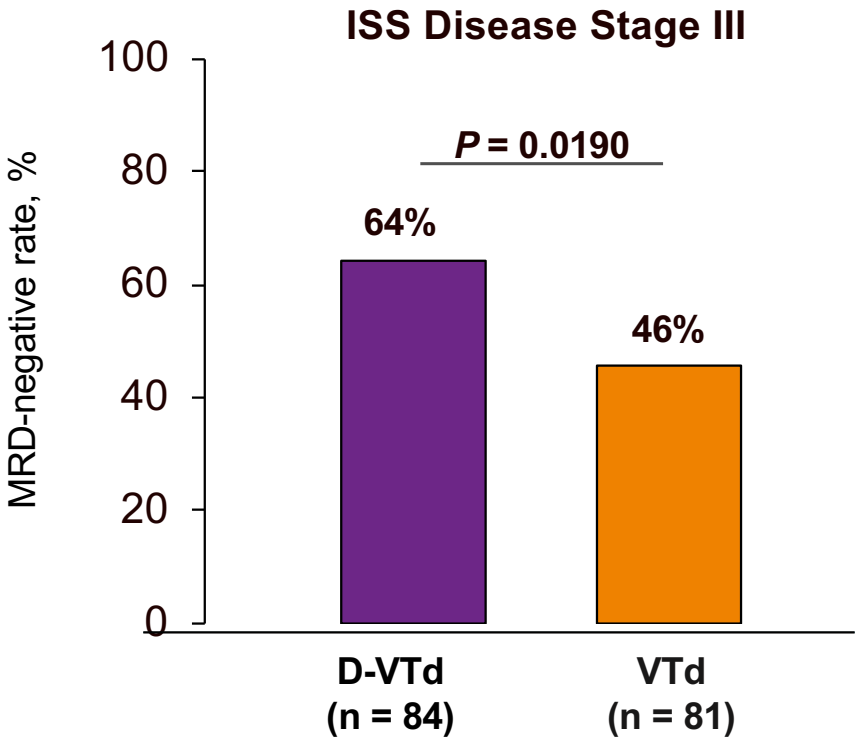
Post-consolidation MRD (Flow Cytometry; 10^{-5})

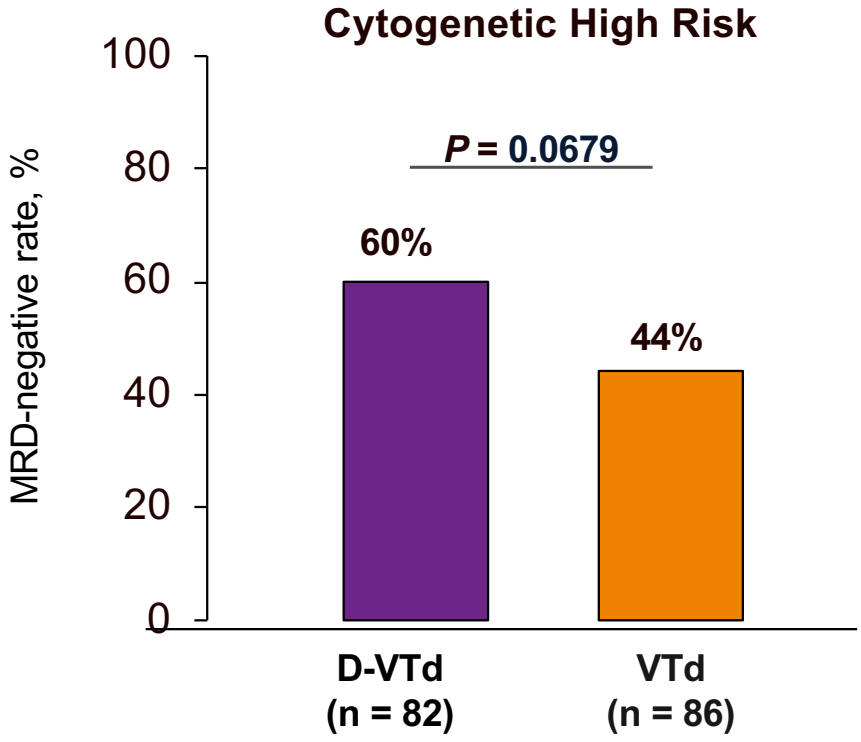


Higher proportions of patients achieved MRD negativity with D-VTd

MRD analyses were performed on bone marrow aspirates post-consolidation.
Additional MRD results will be presented immediately following this presentation at the Main Plenary Session: Avet-Loiseau H, et al. IMW 2019. Oral presentation OAB-004.

Post-consolidation MRD in High-risk Subgroups (Flow Cytometry; 10^{-5})





MRD-negativity rates were superior with D-VTd in patients with high-risk cytogenetics and ISS stage III disease

Additional MRD results will be presented immediately following this presentation at the Main Plenary Session: Avet-Loiseau H, et al. IMW 2019. Oral presentation OAB-004.

Can we abrogate High-Risk MM by making the right treatment choices?

- Choice of drugs and schedule
- Continuous treatment
- Maintenance treatment
- MRD guided treatment
- Allo-SCT - Immune therapies

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Strategies to overcome HR disease

Evidence based

- Single HDM/ASCT = standard; Double HDM/ASCT for patients with HR-FISH/R-ISS3 (Cavo et al., ASH 2018)
- Quadruple regimens including PI, IMiD, MoAb for induction (Moreau et al., Lancet 2019)
- Tandem auto-allo for HR-FISH (Knop et al., Leukemia 2019)
- The impact must be achieved during initial treatment before RRMM

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Potential strategies to overcome HR disease

Hypothesis based

- Continuous treatment with alternating regimens/schedules
- Change of regimen if no CR/sCR or MRD negativity
    - At the end of induction (TE-MM + TNE-MM)
    - Upgrade to experimental therapy (immune) if response suboptimal

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Relevant facts for clinical practice and drug choices in patients with High-Rish FISH

Proteasome inhibitors

- Improve PFS/OS for t(4;14)
- Carfilzomib may improve PFS for del17p
- May be less effective for t(14;16) (ISS3)

Immunomodulatory drugs

- Thal/Len/Pom do not improve PFS/OS for t(4;14)
- Pom may abrogate del17p for PFS/OS (RRMM)

High Dose Melphalan/ASCT

- Mel200 superior with RVd induction/consolidation
- Tandem may abrogate t(4;14) along with PI based induction/maintenance
- Tandem may help in del17p, however TP53 status is important

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Relevant facts for clinical practice and drug choices in patients with High-Rish FISH

Antibodies

- Improve PFS (and OS), MRD in SR and HR
- Daratumumab improves outcome across subgroups, offers a better prognosis for HR

Targeted therapy

- Venetoclax for t(11;14), bcl-2/XL, MCL-1
- MYC, MAPK etc too early, Selinexor

Immune therapy

- Checkpoint inhibitors poor balance between efficacy and safety
- CAR-T cell and other BCMA directed treatment
- Bites under investigation

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Conclusions

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Up-front CART-BCMA With or Without huCART19 in High-risk Multiple Myeloma

ClinicalTrials.gov Identifier: NCT03549442

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

Recruitment Status : Recruiting
First Posted : June 8, 2018
Last Update Posted : April 18, 2019

See **Contacts and Locations**

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