EHA®2021 Virtual

Prezentací 2 025

Abstraktů 1 715

EP1009 IDECABTAGENE VICLEUCEL (IDE-CEL, BB2121), A BCMA-DIRECTED CAR T CELL THERAPY, IN PATIENTS WITH RELAPSED AND REFRACTORY MULTIPLE MYELOMA: UPDATED KARMMA RESULTS

Albert Oriol, Jesus San-Miguel, Ankit Kansagra et al.

– report updated efficacy and safety data from the phase 2 KarMMa trial (NCT03361748);

– of the 140 patients enrolled in KarMMa, 128 received ide-cel;

– the ORR was 73% and the median PFS was 8.8 months;

– at the highest target dose (450 × 10 6 CAR+ T cells), the ORR was 81%, the CR rate was 39%, and the median PFS increased to 12.2 months;

– responses were observed in all subgroups, including difficult-to-treat subsets (e. g. high tumor burden [ORR, 71%], extramedullary disease [70%], and R-ISS stage III disease [48%]);

– estimated 15-month OS rate was 71%.

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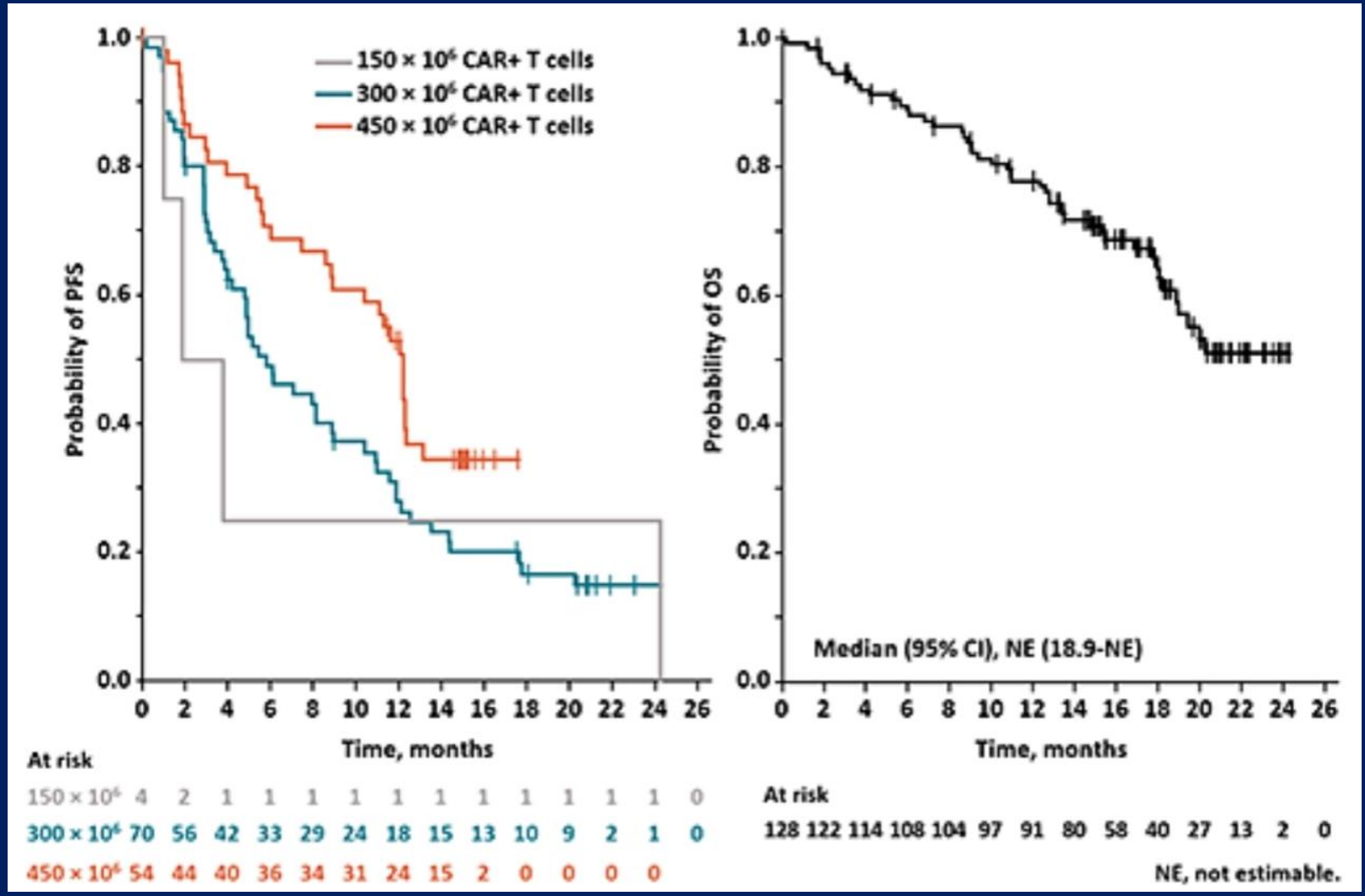
IDE-CEL, B, A BCMA-DIRECTED CAR T CELL THERAPY, IN PATIENTS WITH RELAPSED AND REFRACTORY MULTIPLE MYELOMA: UPDATED KARMMA RESULTS

Dose, × 10^6 CAR+ T cells	150 (n = 4)	300 (n = 70)	450 (n = 54)	300-450 (n = 124)	Total (N = 128)
ORR, n (%)	2 (50)	48 (69)	44 (81)	92 (74)	94 (73)
CR/sCR, n (%)	1 (25)	20 (29)	21 (39)	41 (33)	42 (33)
Median DOR, mo*	†	9.9	11.3	10.7	10.7
Median PFS, mo*	†	5.8	12.2	8.8	8.8

*Kaplan-Meier estimate. †Not reported due to small n.

IDE-CEL, B, A BCMA-DIRECTED CAR T CELL THERAPY, IN PATIENTS WITH RELAPSED AND REFRACTORY MULTIPLE MYELOMA: UPDATED KARMMA RESULTS



EP990 COMPARISON OF CILTACABTAGENE AUTOLEUCEL VERSUS CONVENTIONAL TREATMENT IN PATIENTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA

Luciano Costa, Yi Lin, Tom Martin et al.

– analyses were performed on the intent-to-treat (ITT) population in CARTITUDE-1, defined as patients who underwent apheresis (N = 113), and a modified ITT (mITT) population, defined as the subset of patients who received cilta-cel at the recommended phase 2 dose (N = 97);

– CARTITUDE-1 ITT cohort had improved PFS (12 months, 73% vs. 12%) and OS (12 months, 83% vs. 39%).

EP978 MATCHING ADJUSTED INDIRECT COMPARISON OF CILTACABTAGENE AUTOLEUCEL VERSUS BELANTAMAB MAFODOTIN IN PATIENTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA (RRMM) TREATED WITH ≥ 3 LINES OF PRIOR THERAPY **Katja Weisel, Amrita Krishnan, Kwee Yong et al.**

- patients from CARTITUDE-1 (N = 85) who matched the eligibility criteria for DREAMM-2 (≥ triple-class refractory and refractory to last line of treatment);

– analyses demonstrated improved efficacy with cilta-celversus belantamab mafodotin for ORR, ≥ CR, PFS, and OS.

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	ITT (apheresis) CARTITUDE-1 (N=95)	ITT matches, MAMMOTH (N=95)		mITT (treated) CARTITUDE-1 (N=69)	mITT matches, MAMMOTH (N=69)	
Mean Age -years (sd)	62.4 (8.5)	62 (8.5)		62.6 (7.7)	62.7 (9.4)	
High cytogenetic risk	22%	24%		25%	23%	
Mean N lines of therapy (sd)	6.2 (3.0)	6.3 (2.4)		5.9 (2.9)	6 (1.9)	
Triple-class refractory	97%	96%		96%	96%	
Penta exposed	80%	76%		75%	75%	
Penta refractory	43%	42%		35%	42%	
ORR	84%	28%	P<0.001	96%	30%	P<0.001
PFS	HR=0.11, 95% C.I. 0.05-0.22		P<0.001	HR=0.02, 95% C.I. 0.01-0.14		P<0.001
OS	HR=0.20, 95% C.I. 0.10-0.39		P<0.001	HR=0.05, 95% C.I. 0.01-0.22		P<0.001

C.I., confidence interval; HR, hazard ratio; ITT, intent-to-treat; mITT, modified intent-to-treat; N, number; ORR, overall response rate; OS, overall survival; PFS, progression free survival; sd, standard deviation.

Comparison between efficacy outcomes for cilta-cel from the CARTITUDE-1 study to the approved 2.5 mg/kg (every 3 weeks) dose of belantamab mafodotin from the DREAMM-2 trial

Outcome*	Cilta-cel vs. belantamab mafodotin 2.5 mg/kg
ORR, OR (95% CI)	270.65 (74.64, 981.41)†
≥CR, OR (95% CI)	59.17 (15.17, 230.76)†
PFS, HR (95% CI)	0.21 (0.11, 0.40)†
OS, HR (95% CI)	0.22 (0.10, 0.46)†

*Patient populations from CARTITUDE-1 (N=85, ≥ triple-class refractory and refractory to last line of treatment) and DREAMM-2 (N=97) were matched on refractory status, cytogenetic risk, EMD, and ISS; †$P<0.0001$.

CR, complete response; CI, confidence interval; EMD, extramedullary disease; HR, hazard ratio; ISS, international staging system; OR, odds ratio; OS, overall survival; PFS, progression-free survival.

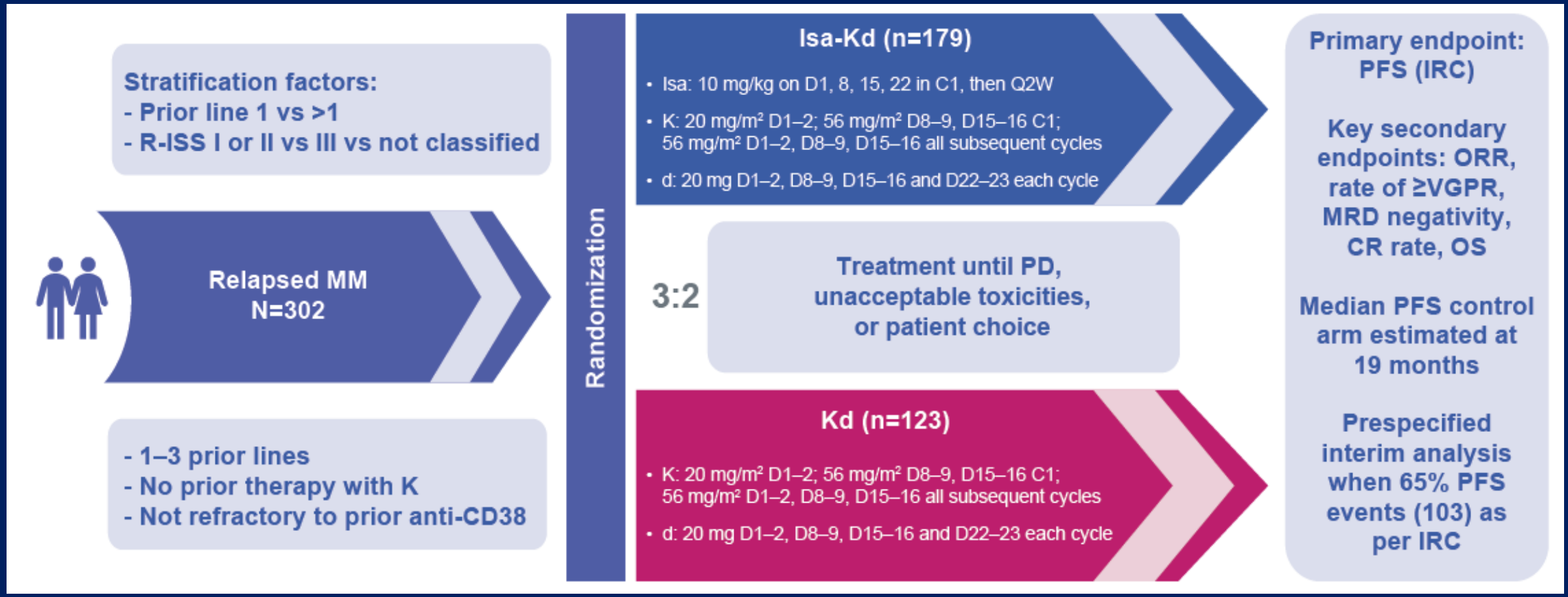
Isatuximab plus carfilzomib and dexamethasone in relapsed multiple myeloma patients with high-risk cytogenetics: IKEMA subgroup analysis

Ivan Spicka[1], Philippe Moreau[2], Thomas G. Martin[3], Thierry Facon[4], Gracia Martinez[5], Albert Oriol[6], Youngil Koh[7], Andrew Lim[8], Gabor Mikala[9], Laura Rosiñol[10], Münci Yağci[11], Michele Cavo[12], Marie-Laure Risse[13], Gaëlle Asset[14], Sandrine Macé[13], Helgi van de Velde[15], Kwee Yong[16]

Presentation at the American Society of Clinical Oncology (ASCO®) Annual Meeting 2021, Virtual, June 4–8, 2021

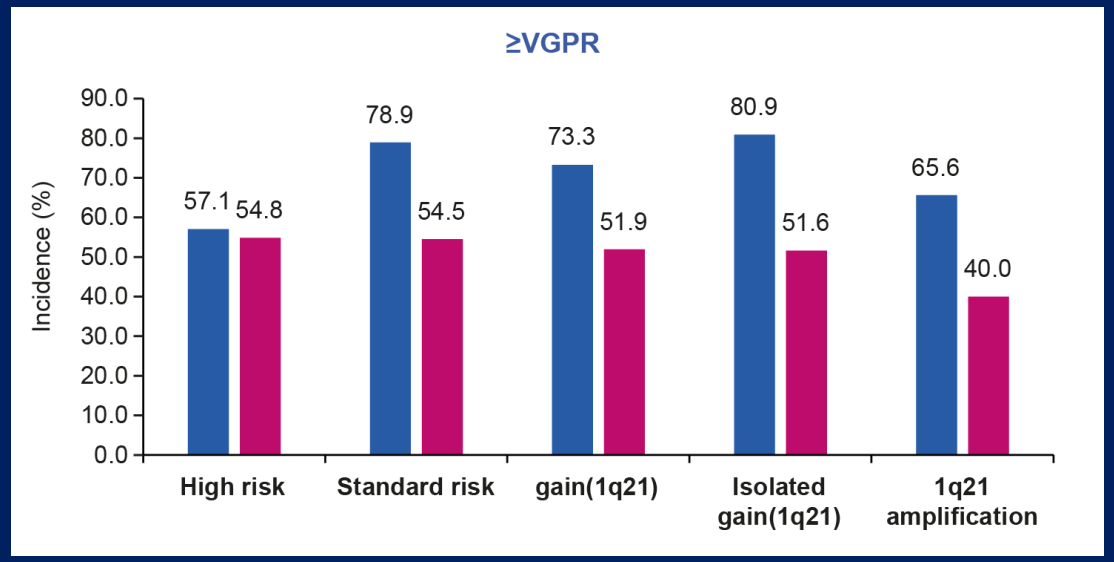
Abstract: 8042

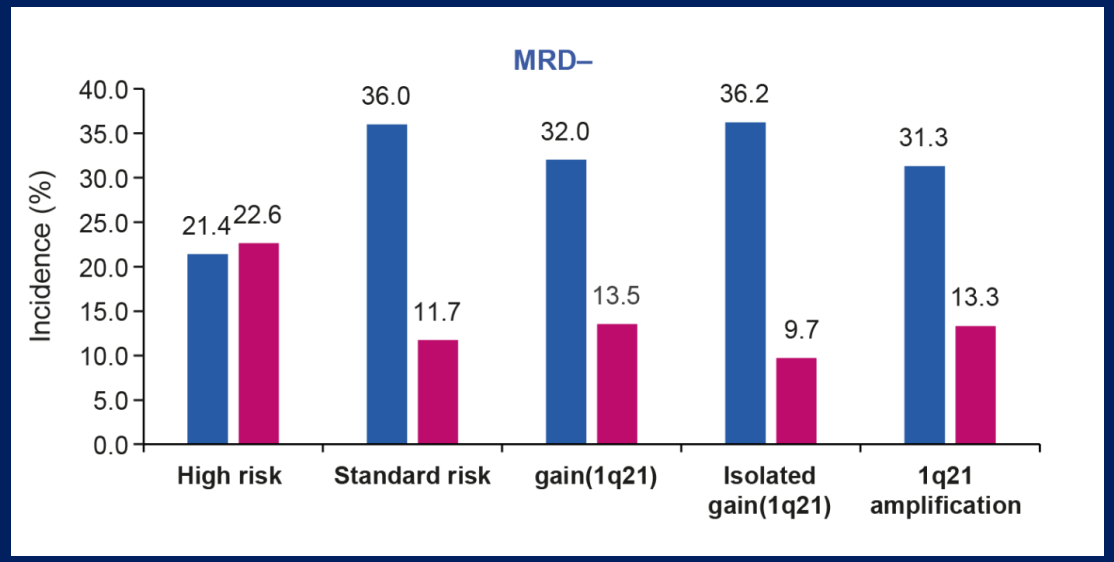
Study design: Isa-Kd vs. Kd in relapsed multiple myeloma

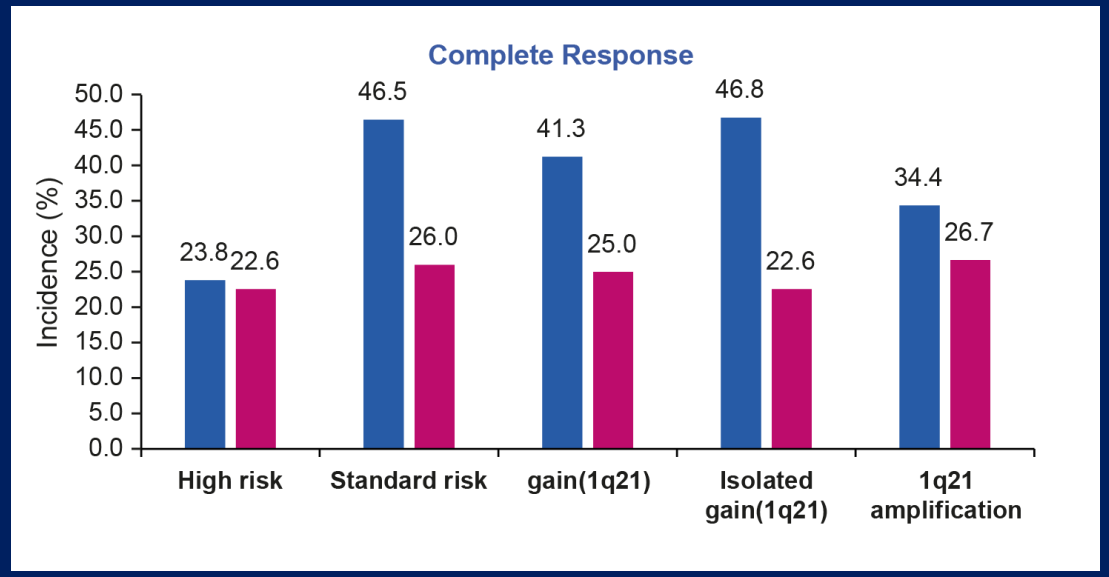


Sample size calculation: ~300 patients and 159 PFS events to detect 41% risk reduction in hazard rate for PFS with 90% power and one-sided 0.025 significance level

Depth of response







IKEMA
Summary

- **The addition of Isa to Kd improved PFS in patients with high-risk cytogenetics [del(17p), t(4;14), and/or t(14;16)].**
- **The addition of Isa to Kd improved PFS and depth of response in patients with gain or amplification of 1q21, which is approximately 40% of patients with MM and an unmet need[1].**
- **These findings were consistent with the benefit observed in the overall IKEMA population.**
- **Isa-Kd had a manageable safety profile in these patients.**

Isa-Kd represents a treatment option for the difficult-to-treat subgroup of patients with RMM and high-risk cytogenetics.

LB1901 OVERALL SURVIVAL RESULTS WITH DARATUMUMAB, LENALIDOMIDE, AND DEXAMETHASONE VERSUS LENALIDOMIDE AND DEXAMETHASONE IN TRANSPLANTINELIGIBLE NEWLY DIAGNOSED MULTIPLE MYELOMA: PHASE 3 MAIA STUDY

Thierry Facon, Shaji K. Kumar, Torben Plesner et al.

– the primary analysis of MAIA, DARA plus lenalidomide and dexamethasone (D-Rd) reduced the - risk of disease progression or death by 44% versus lenalidomide and dexamethasone (Rd).

– almost 5 years of median follow-up (56,2 mo)

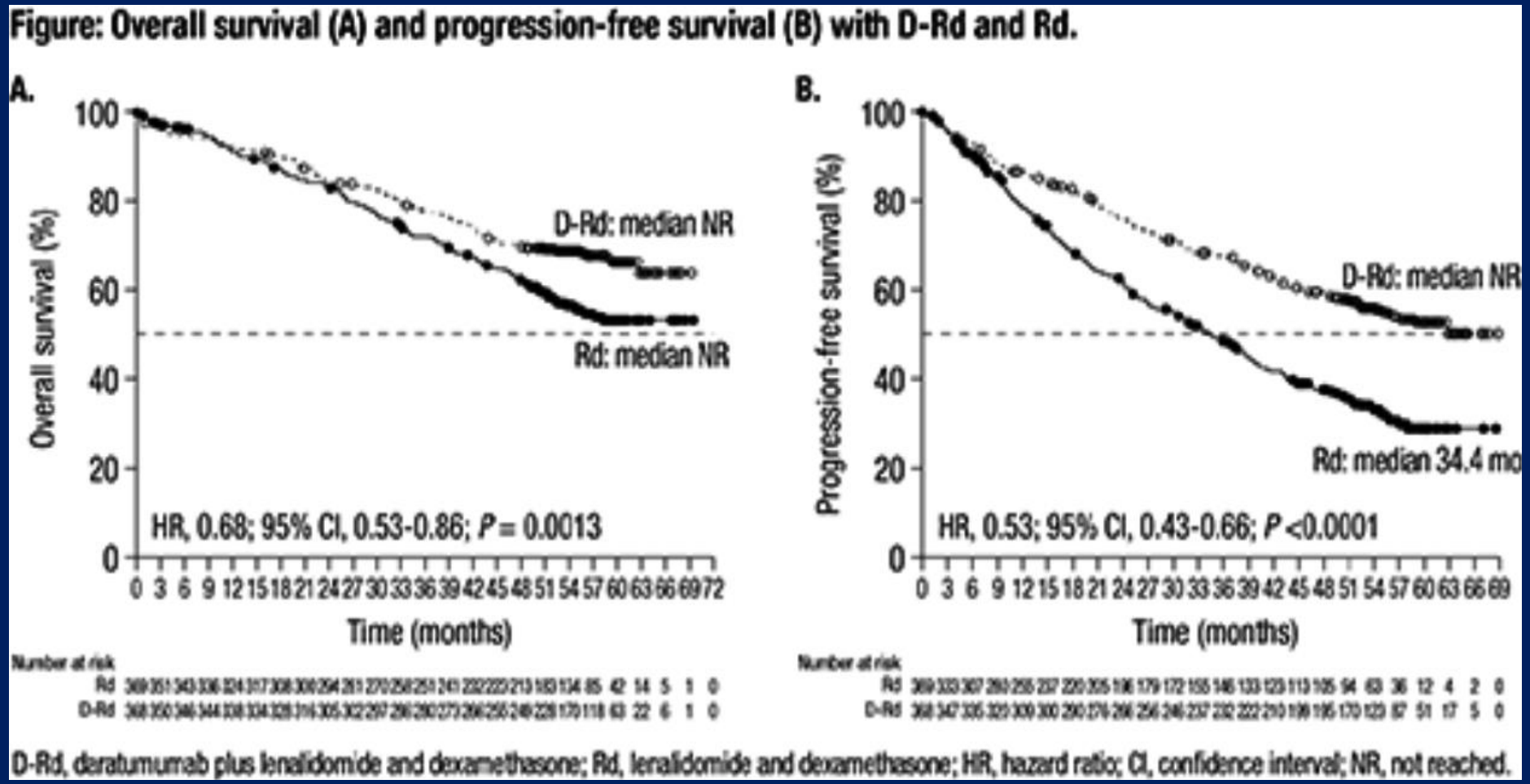
– 737 patients (D-Rd, 368; Rd, 369)

– 32% reduction in the risk of death was observed with D-Rd

– estimated 5-year OS rate was 66.3% with D-Rd and 53.1% with Rd

– updated median PFS was NR with D-Rd versus 34.4 months with Rd (HR, 0.53)

Celkové přežití (A) a přežití bez progrese (B)



EP816 COVID-19 INFECTION IN MULTIPLE MYELOMA PATIENTS – CZECH EXPERIENCE Topic: 30. Infectionsin hematology (incl. supportive care/therapy)

Jakub Radocha , Ludek Pour, Tomas Jelinek, Ivan Spicka, Alexandra Jungova, Jiri Minarik, Adriana Heindorfer, Jana Ullrychova, Petr Kessler, Marek Wrobel, Jarmila Obernauerova, Michal Sykora, Lukas Stejskal, Vladimir Maisnar, Roman Hajek

– 158 patients with MM and COVID-19 with known outcome of the infection were identified;

– there were 72.8% (115/158) survivors and 27.2% (43/158) deceased patients;
– non-survivors were significantly older (median 71.5 years vs. 67.9 years, p = 0.046);
– there were no differences between previous treatment lines in either group;
– survivors hospitalization rate was 31.3% (36/115) and 88.4% (38/43) in non-survivors;

– in-hospital mortality was 51.4% (38/74);
– non-survivors had more intensive care unit stays (4.3% vs. 55.8%).

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Type of care	Survivors (n=115)	%	Non-survivors (n=43)	%	p value
Outpatient (N, %)	79	68.7	5	11.6	<0.0001
Hospitalized (N, %)	36	31.3	38	88.4	<0.0001
Standard ward (N, %)	33	28.7	16	37.2	0.4029
ICU (N, %)	5	4.3	24	55.8	< 0.0001
Length of stay (median, range)	11	(4-40)	10	(2-42)	0.4691
Oxygen support					
Without O2 (N, %)	85	73.9	5	11.6	< 0.0001
NIV / HFNO (N, %)	3	2.6	17	39.5	< 0.0001
ALV (N, %)	1	0.9	10	23.3	< 0.0001
Oxygen (low flow) (N, %)	19	16.5	19	44.2	0.0006
Symptoms of COVID-19					
Symptomatic (N, %)	76	66.1	39	90.7	0.0038
Fever (N, %)	49	42.6	29	67.4	0.0093
Cough (N, %)	38	33.0	26	60.5	0.0033
Dyspnea (N, %)	24	20.9	28	65.1	< 0.0001
Chills (N, %)	3	2.6	3	7.0	0.4174
Muscle pain (N, %)	11	9.6	2	4.7	0.4995
Headache (N, %)	13	11.3	3	7.0	0.6127
Sore throat (N, %)	1	0.9	0	0.0	0.6076
Loss of taste or smell (N, %)	12	10.4	1	2.3	0.1849
Treatment					
Convalescent plasma (N, %)	2	1.7	2	4.7	0.6397
Hydroxychloroquine (N, %)	0	0.0	1	2.3	0.6076
Remdesivir (N, %)	7	6.1	7	16.3	0.0907
Complications					
Bacterial superinfection (N, %)	11	9.6	15	34.9	0.0003
Relation to neutropenia (N, %)	0	0.0	3	7.0	0.0275
Thrombotic complications (N, %)	0	0.0	2	4.7	0.1265

ICU: intensive care unit, NIV: non-invasive ventilation, HFNO: high-flow nasal oxygen, ALV: artificial lung ventilation

Děkuji za pozornost.