will be excluded for different reasons and anyway it will help for future analyses if the number of registers is higher.

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MYELOMA

OP 04

UPDATED PROGRESSION-FREE SURVIVAL (PFS) AND DEPTH OF RESPONSE IN IKEMA, A RANDOMIZED PHASE 3 TRIAL OF ISATUXIMAB, CARFILZOMIB AND DEXAMETHASONE (ISA-KD) VS KD IN RELAPSED MULTIPLE MYELOMA (MM)

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Objective: The anti-CD38 antibody Isa in combination with Kd is approved in various countries for patients (pts) with relapsed MM after ≥1 prior therapy, based on primary interim analysis (IA) of the Phase 3 IKEMA study (NCT03275285). Here we report updated efficacy and safety Results from IKEMA. **Methodology:** This prespecified final analysis (Isa-Kd 179, Kd 123 pts) evaluated updated PFS (primary endpoint), PFS2, CR rate, MRD- rate, and MRD- and CR rate in ITT population, and safety with 2 additional years of follow-up. Isa 10mg/kg was given IV qw for 4 wks and then q2w; Kd 20/56mg/m^2 biw, 3/4 weeks. Hydrashift Isa IF assay was used to rule out potential Isa interference in CR determination. At cutoff (14Jan2022; median follow-up 44 mo), 49 (27.4%) Isa-Kd, 11 (8.9%) Kd pts were still on treatment. **Results:** Updated PFS was consistent with primary IA Results, showing significant benefit of Isa-Kd (vs Kd): PFS HR 0.58; PFS2 HR 0.68. Final CR rate (Isa-Kd vs Kd) was 44.1% vs 28.5%, MRD- rate 33.5% vs 15.4%, MRD- and CR rate 26.3% vs 12.2% (***Table***). Serious TEAEs were reported in 70.1% Isa-Kd vs 59.8% Kd pts. The most common, any-grade non-hematologic TEAEs in Isa-Kd were infusion reactions (45.8%), diarrhea (39.5%), hypertension (37.9%) and upper respiratory tract infection (37.3%). **Conclusion:** These Results show unprecedented mPFS, CR rate, MRD- and MRD- CR rates in a non-lenalidomide containing regimen with benefit maintained through subsequent therapies and a manageable safety profile. Safety profiles and efficacy Results in both arms were consistent with prior IKEMA findings. Our findings support Isa-Kd as a standard of care treatment for pts with relapsed MM.

	Isa-Kd n=179	Kd	
Median PFS, months	35.7 (28.8-44.0)	19.2 (15.8-25.0)	HR (95.4% CI) 0.58 (0.42-0.79)
Median, PFS2, months	47.2 (38.1-NC)	35.6 (34.0-40.5)	HR (95% CI) 0.68 (0.50-0.94)
	n (%) 95% CI	n (%) 95% CI	odds ratio 95% CI
ORR	155 (86.6) 0.81-0.91	103 (83.7) 0.76-0.90	-
CR	79 (44.1) 0.37-0.52	35 (28.5) 0.21-0.37	2.09 1.26-3.48
MRD-rate	60 (33.5) 0.27-0.41	19 (15.4) 0.10-0.23	2.78 1.55-4.99
MRD and CR rate	47 (26.3) 0.20-0.33	15 (12.2) 0.07-0.19	2.57 1.35-4.88

Table: Efficacy (ITT)
CI confidence Interval, HR hazard ratio, ITT intent to treat, NC not calculable, ORR overall response rate

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STEM CELL TRANSPLANT

OP 05

PEDIATRIC ACUTE MYELOID LEUKEMIA (AML): NOTCH1 ACTIVATION INFLUENCING PROGNOSIS THROUGH TRANSFORMING GROWTH FACTOR-B (TGF-BETA) / SETBP1; REPORT OF A PILOT STUDY FROM SAUDI ARABIA

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