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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Objective: NOTCH1 is now established to play a key role in the prognosis of several hematological malignancies. Notch proteins are multifaceted and involved in several key cellular functions with extensive crosstalk with other critical pathways; therefore, it is important to investigate NOTCH1 expression and its influence on other oncogenic pathways molecules in AML. In this pilot study, we correlated NOTCH1 and associated pathway expression patterns among childhood AML patients and correlated it with hematological parameters and overall survival (OS) data. **Methodology:** RNA from diagnostic BM biopsies (n=35) were subjected to expression analysis employing nCounter Pan-Cancer pathway panel by Nanostring technologies. Laboratory and clinical data were correlated with expression of NOTCH1 and several other oncogenic signaling pathways (n=780). nSolver software v3 and SPSS software v24.0 were utilized for statistical evaluation. Hierarchical clustering and principle component analyses were performed employing Qlucore Omics Explorer v3.2. **Results:** 35 -AML patients (median age 8 yrs., range <1-18 yrs.) were dichotomized into low NOTCH1 (17/35; 49%) and high NOTCH1 (18/35; 51%) groups based on receiver operating characteristic (ROC) curve analysis (74% AUC; 82% sensitivity /68% specificity). Age, gender, hematological data or molecular risk factors (FLT3 mutation/molecular fusion) exposed no significant differences across these two distinct NOTCH1expression groups (P > 0 .05). High NOTCH1 expression was linked with high expression of NOTCH1 legend (Dll1) (P<0.001/fold >2.5). Our data also showed that high NOTCH1 mRNA is interrelated with heightened expression of positive regulator of the NOTCH signaling pathway (DTX1/DTX3). High NOTCH1 samples also showed high expression of TGRF-b associated protein SETBP1(P<0.001/fold >2.5) (Figure 1A). The level of NOTCH1 expression did not correlate with mortality {5/17 (29%) vs. 6/17; (35%) P > 0.05}. Low NOTCH1 expressers showed better OS {740 days vs. 579 days; log-rank P=< 0.007; HR 6.3 (1.36-29.26)} **Conclusion:** Our pilot study identified high Notch1 expression through canonical pathway as an important poor prognostic marker among pediatric AML patients which is independent of conventional prognostic markers and can provide insights into novel potential therapeutic target. Our study has identified that high expression of the molecules linked with NOTCH1 pathway are an important poor prognostic marker among childhood AML patients. NOTCH1 expression also shows cross talk with several other signal transduction pathways especially TGFb / SETBP1 which are also linked with poor prognosis.

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OP 06

EVALUATION OF COVID-19 FEAR AND QUALITY OF LIFE IN PATIENTS WITH HEMATOPOIETIC STEM CELL TRANSPLANTATION DURING THE COVID-19 PANDEMIC

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Objective: The coronavirus disease 2019 (COVID-19) pandemic has an impact on physical health, but also has effects on mental health. With the COVID-19 pandemic, the level of fear increases and fear triggers many psychological diseases such as depression. We aimed to determine the COVID-19 fear situation in hematopoietic stem cell transplantation (HSCT) patients and to examine its relationship with the quality of life. **Methodology:** In this prospective study, 64 patients who underwent HSCT during the pandemic (between 11 March 2020 and 31 December 2020) were included. The COVID-19 fear situation was evaluated with the Fear of COVID-19 Scale (FCV-19S). Quality of life was evaluated with the European Organization for Quality of Life Research and Treatment Core Questionnaire (EORTC QLQ-C30) (version 3). **Results:** The median FCV-19S score was 16.5 (12.0-22.0). The FCV-19S score was significantly higher in urban residents than rural residents (19.0 (15.0-23.5) vs 14.0 (9.0-22.0) (p=0.44). The general health score was 59.64 ± 20.04. The strongest positive correlation between fear level and quality of life was found in emotional function (r=0.474, p <0.01). In addition, a weak, significant, positive correlation was observed between role function, nausea-vomiting, pain, anorexia, and fear level. **Conclusion:** FCV-19S is a short, safe and valid tool that can be used to determine the COVID-19 fear level in vulnerable patient groups such as HSCT patients and to direct them to the necessary psycho-oncological support.

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OP 07

UMBILICAL CORD BLOOD (UCB) AND BONE MARROW (BM) AS A SOURCE OF NATURAL KILLERS (NK) FOR KIR-ALLOREACTIVE ADOPTIVE IMMUNOTHERAPY (KIR-AI)

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Objective: NK are innate lymphoid cells with the ability to rapidly recognize and exhibit cytotoxicity toward tumor and virus infected cells in HLA-independent manner without prior activation. KIR-AI is the next promising step after KIR-alloreactive NMAC alloBM transplantation (not only in hematology). We evaluate NK amount, the balance of activating and inhibitory receptors (rp) of different sources, outcomes of KIR-AI UCB/BM. **Methodology:** NK UCB, BM, peripheral blood (PB) were evaluated by flow cytometry (CD3, 7, 16, 56, 94, NKG2A),