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Acute Leukemias

FIRST INTERIM ANALYSIS OF VENETOCLAX REAL-WORLD OBSERVATIONAL STUDY ON NEWLY-DIAGNOSED ACUTE MYELOID LEUKEMIA PATIENTS IN ITALY (VERO)

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Introduction: Venetoclax+Azacitidine (Ven/Aza) is approved as standard of care in Italy for Newly Diagnosed (ND) acute myeloid leukemia (AML) adult patients (pts) ineligible for intensive chemotherapy (IC). The multicenter VERO study collects prospective real-world data on Ven/Aza management, effectiveness, safety and quality of life (QoL).

Methods: Twenty-five Italian clinical sites enrolled 151 patients. Inclusion criteria: ND IC-ineligible AML; independent investigator's treatment choice according to local label. This interim analysis (IA) was conducted after 50% of pts had ≥3-months (mos) of follow-up (cut-off: 27Jan25), reporting baseline features/QoL data (EORTC QLQ C-30/EQ-5D-5L), Ven/Aza treatment management, Tumor Lysis Syndrome (TLS) risk assessment and early effectiveness/safety data.

Results: 75 pts were analyzed: mean age was 76.2(±6) years; 24% >80 years, 48% 75-80 years; 70.7% of pts had de novo AML and 29.3% a secondary AML. Molecular tests reported mutations for NPM1-TP53-IDH1/2-FLT3. ELN2022 risk classification: intermediate in 16pts (21%), adverse in 41(55%), missing in 18. Mean baseline QoL scores showed moderate global health, higher cognitive and lower physical functioning. In C1: 73 evaluable pts received Ven with a 28 days(dd) median treatment duration (IQR: 21-28), median dose 133.3mg/d (IQR:100-225). In C2: 50pts treated for a median of 28dd (IQR:22-28), median dose 100mg/d (IQR:100-233). In C3: 45pts treated for a median of 28dd (IQR:21-28), median dose 200mg/d (IQR:100-400). Aza: median of 75mg/7 dd. Antifungal prophylaxis was given to 51/75pts (68%) (Tab1), and G-CSF to 27/47(55%).

Overall Response Rate (ORR): 58.7% (44/75pts). Composite Complete Remission (cCR:CR+Cri+CR and Cri MRD-) 53.8% (25/65pts).

Median time to best response: 0.95 mos (IQR:0.7- 1.9); 65pts (86.7%) had at least 1 response assessment post C1. Measurable residual disease (MRD, mainly performed by flow cytometry): C1 - 8/31pts tested (25.8% MRD-), C2 - 4/14(28.6%MRD-), C3 - 3/10 (30%MRD-). Transfusion independence (>56dd): mo 1=77.8%, mo 2=42.6%, mo 3=58.8%. 3pts underwent bone marrow transplant. 3-Months OS estimate (95% CI):0.73 (0.61, 0.82) (Fig1).

AEs of interest included cytopenia: 51.7% (31/60) - mostly febrile neutropenia (48.4%), neutropenia (51.6%); overall infection rate: 66.7% (57 pts), 81.6% bacterial, 5.3% fungal. Study discontinuation: 26.7% (20 pts) - mainly for infections (55%), cytopenia (15%). 26 reported deaths: mainly for progression (8), septic shock (6).

Conclusions: The interim analysis describes the first 50% of pts from the VERO study, mainly elderly pts with de novo and sAML. Despite the short follow-up and limited sample size, data show Ven/Aza effectiveness in the real-world setting. Median time to response was <1mo, showing timely response assessment in real life. No new safety signals were reported. Our findings, though only descriptive, align with published real-world and clinical trial data1-2.

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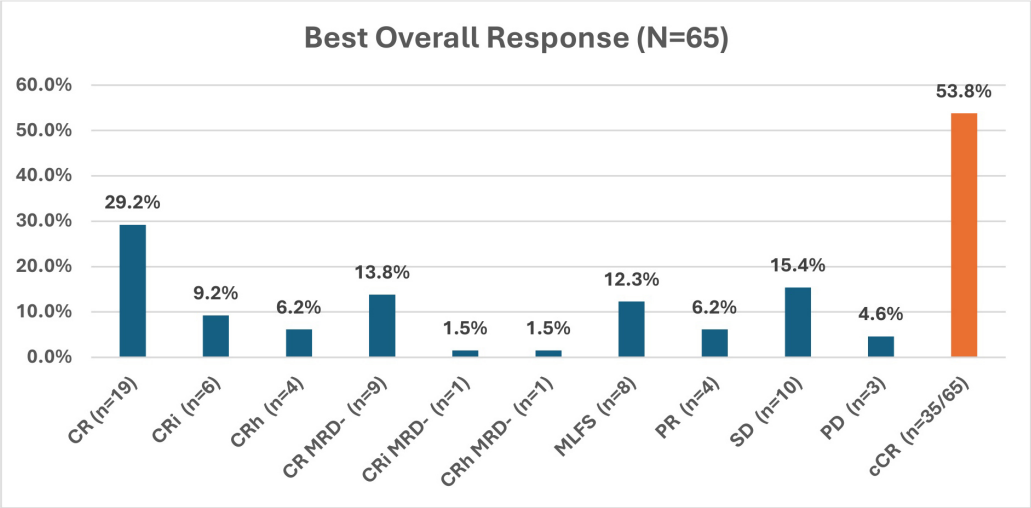
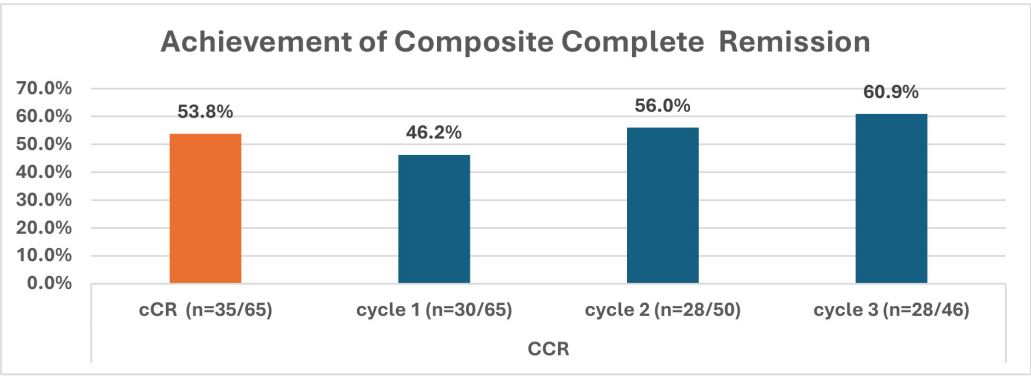
Figure 1: A) Best Overall Response; B) Composite Complete Remission;

A



Best Overall Response Rate: frequency of patients achieving CR without MRD (CRMRD-), CRh without MRD (CRhMRD-), CRi without MRD (CRiMRD-), Complete Remission (CR), Complete Remission with partial hematologic recovery (CRh), Complete Remission with incomplete hematological recovery (CRi) and Partial Remission (PR) up to the cut-off date

B



n=number of patients reaching cCR/number of patients with a cycle response assessment completed