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ORAL ABSTRACTS

615.ACUTE MYELOID LEUKEMIAS: COMMERCIALLY AVAILABLE THERAPIES, EXCLUDING TRANSPLANTATION AND CELLULAR IMMUNOTHERAPIES

Venetoclax Combined with Daunorubicin and Cytarabine (2 + 6) in Acute Myeloid Leukemia: Updated Results of a Phase II Trial

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INTRODUCTION

Venetoclax (Ven) combined with intensive chemotherapy had been proven effectively in the management of newly diagnosed acute myeloid leukemia (AML). Our previous study showed that Ven combined with DA (2 + 6) is a highly effective and safe induction therapy for adults with newly diagnosed AML. To further validate the efficacy and safety of this induction regimen, the study continued to enroll young patients with newly diagnosed AML. Now, we have updated the results of this phase 2, multicenter, single-arm trial.

METHODS

Details of the Study design, participants, inclusion and exclusion criteria, procedures, efficacy and safety evaluation were provided in our previous article "Venetoclax combined with daunorubicin and cytarabine (2 + 6) as induction treatment in adults with newly diagnosed acute myeloid leukemia: a phase 2, multicenter, single-arm trial" which published in the Journal of "Experimental Hematology & Oncology".

RESULTS

Until June 30, 2023, seventy patients were enrolled and treated with Ven combined with DA (2 + 6) as induction therapy. The median age was 44 (range, 16-60) years, and 37 (52.9%) patients were male. According to the European Leukemia Network prognostic group (2022), 32 (45.7%), 9 (12.9%), and 29 (41.4%) patients were considered to belong to the favorable, intermediate, and adverse groups, respectively.

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The ORR after one cycle of induction was 92.9% (65/70)with a composite complete response rate (CR + CRi) of 90.0% (CR 61/70, CRi 2/70). Moreover, 89.5% (51/57) of the patients reached CR with undetectable MRD. Grade 3 or worse adverse effects included neutropenia (100%), thrombocytopenia (100%), febrile neutropenia, and one mortality. The median neutrophil and platelet recovery times were 13 (5-36) and 13 (8-48) days, respectively. (Table 1)
Until Jan 30, 2023, with with a median follow-up of 9 (1-18) months, 6 patients proceed Allo-HSCT, the estimated 12-month OS, EFS, and DFS rates were 84.9%, 81.0%, 81.6%, respectively. (Figure 1)
Conclusion: Ven with DA (2 + 6) is a highly effective and safe induction therapy for adults with newly diagnosed AML.
Keywords **Venetoclax, DA(2+6), induction treatment, acute myeloid leukemia**

Disclosures No relevant conflicts of interest to declare.

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Table 1 Response Assessment

	Overall (n=70)	Favorable risk (n=32) *	Intermediate risk (n=9) *	Adverse risk (n=29) *
Overall response rate (CR+CRi+PR)	92.9% (65/70)	96.0% (31/32)	77.8% (7/9)	93.1% (27/29)
composite complete remission rate	90.0% (63/70)	96.0% (31/32)	77.8% (7/9)	86.2% (25/29)
CR	87.1% (61/70)	96.0% (31/32)	77.8% (7/9)	79.3% (23/29)
CRi	2.9% (2/70)	0	0	6.9% (2/29)
PR	2.9% (2/70)	0	0	6.9% (2/29)
Died	1.4% (1/70)	0	0	3.4% (1/29)
MRD (-) after induction by flow cytometry	89.5% (51/57)			
Responders that received allo-HSCT	6/69 (8.7%)			
Time to blood cell count recovery after induction, days				
Time to absolute neutrophil count ≥ 0.5×10^9/L, days	13 (5-36)			
Time to absolute platelet count ≥ 30×10^9/L, days	13 (8-48)			
Even free survival,				
Median, months	NR	NR	NR	NR
12-month, % (95% CI)	81.0%			
Overall survival				
Median, months	NR	NR	NR	NR
12-month, % (95% CI)	84.9%			

Data are n (%). NR, not reached; CR, complete remission. Cri, complete remission with incomplete blood cell count recovery; PR, partial remission; Allo-HSCT, allogeneic-haematopoietic stem cell transplantation; MRD, measurable residual disease. *European Leukemia Net 2022 risk category.

Figure 1

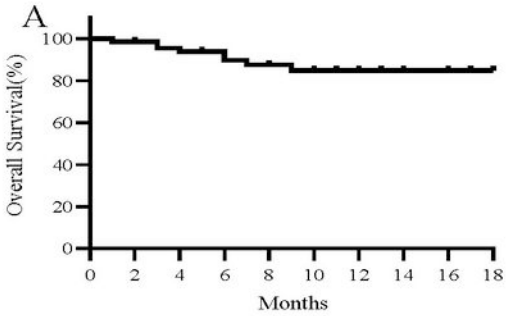

Figure 1 legend: The Kaplan-Meier plot of overall survival (OS) of all patients.

Figure 1

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