Efficacy and Safety of Venetoclax Plus Azacitidine in Acute Myeloid Leukemia Patients Ineligible for Intensive Chemotherapy

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INTRODUCTION

Acute myeloid leukemia (AML) is characterized by clonal proliferation of immature myeloid cells and is associated with poor outcomes in elderly and medically unfit patients. Venetoclax, a selective B-cell lymphoma-2 (BCL-2) inhibitor, in combination with azacitidine, has emerged as an effective low-intensity therapeutic strategy, improving remission and survival outcomes in newly diagnosed AML patients unsuitable for intensive chemotherapy.

AIM

To evaluate the efficacy and safety of venetoclax plus azacitidine in AML patients ineligible for intensive chemotherapy.

METHOD

A review of phase 1b–3 clinical trials, pooled subgroup analyses, and observational studies evaluating venetoclax plus azacitidine in AML patients ineligible for intensive chemotherapy was performed.

Outcomes assessed :

- complete remission/complete remission with incomplete hematologic recovery (CR/CRi)
- overall survival (OS)
- measurable residual disease (MRD) negativity
- treatment-related adverse events.

CONCLUSIONS

Venetoclax plus azacitidine provides durable remissions, meaningful survival benefit, and high response rates in AML patients unsuitable for intensive chemotherapy. Despite frequent hematologic toxicities, the regimen maintains a manageable and predictable safety profile.

RESULTS

Venetoclax plus azacitidine demonstrated significant clinical activity in newly diagnosed AML patients unfit for intensive chemotherapy.

CLINICAL EFFICACY

MEDIAN OVERALL SURVIVAL (OS)

14.7–16.4 MONTHS

24-MONTH OS: 37.5%

COMPOSITE CR/CRi RATE

66–74%

High response rates across studies

MRD NEGATIVITY (AMONG RESPONDERS)

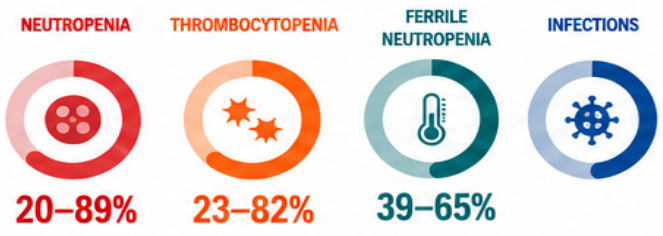
UP TO 80%

Deep responses achieved

CLINICAL BENEFIT ACROSS SUBGROUPS

Maintained in elderly, frail, adverse-risk molecular subgroups, including IDH1/2 mutations

SAFETY PROFILE – MOST COMMON GRADE >3 ADVERSE EVENTS



Gastrointestinal toxicities, particularly nausea, were frequent but predominantly low grade.

No new long-term safety signals were identified.

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CONTACT INFORMATION

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