The Safety and Tolerability of Azacitidine (AZA) Are Comparable in Patients with Acute Myeloid Leukemia (AML) or Higher-Risk Myelodysplastic Syndromes (MDS)

1John F. Seymour, 2Lewis R. Silverman, 3Hartmut Döhner, 4Pierre Fenaux, 5Ghulam J. Mutif, 6Valeria Santini, 7Mark D. Minden, 8Richard M. Stone, 9Lela M. Lucy, 10Stephen Songer, 11Donna Dougherty, 12Randy Hinkle, 13Dominique Gambini, 14C.L. Beach, and 15Hervé Dombret

BACKGROUND

- AML and MDS are distinct, though largely overlapping, diseases, especially in older patients.
- Injectable AZA is recommended 1st-line treatment for patients with higher-risk MDS (HR-MDS) ineligible for hematopoietic stem cell transplantation (HSCT). AZA and AML patients trended toward higher ECOG PS scores and had lower median ANC at baseline, though median platelet and hemoglobin values were similar.

OBJECTIVE

- To determine whether the AZA safety and tolerability profile in older patients with AML is consistent with the well-established safety and tolerability profile of AZA in MDS.

METHODS

- Patients with AML were age ≥65 years with AML and >30% bone marrow (BM) blasts were evaluated in the phase 3 AZA-AML (≥65 years) study (NCT01704947). The European Commission (EC) approved VSDAZA for the treatment of adult patients aged 65 years or older with AML who are not eligible for HSCT.

RESULTS

- Approximately one-third of patients in the AML and MDS studies had a history of cardiovascular disease.
- No new or unexpected safety risks were identified in AZA-treated patients with AML or MDS.
- Higher frequencies of grade 3-4 febrile neutropenia and pneumonia in AZA-AML patients may be due to lower ANC values and more prevalent grade 3-4 neutropenia at study entry compared with patients in AZA-MDS.
- The safety and tolerability of AZA in older patients with AML are consistent with the well-established safety profile of AZA in MDS, suggesting similar approaches can be taken to manage AZA-related TEAEs in patients with AML or MDS.

REFERENCES

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CONCLUSIONS

- Rates of common ATEEs generally decreased with continued treatment in patients with MDS or AML, which may indicate a lack of cumulative toxicity and adverse effects of AZA are attenuated over time.

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CORRESPONDENCE

Please direct any correspondence to the author, John F. Seymour, email: John.Seymour@petermac.org

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