Outcomes in Older Patients With High-risk/Secondary AML Who Achieved Remission With CPX-351 Versus 7+3 but Did Not Undergo Transplant: Phase 3 Exploratory Analysis

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Background

- Standard of care for induction chemotherapy, eg, 7+3 (daunorubicin/cytarabine regimen) are regimens of choice for adults and those with high-risk/refractory AML.²
- CPX-351 (daunorubicin and cytarabine liposomal formulation) for the treatment of adults with newly diagnosed or relapsed AML, ie, AML with hyperdiploid-risk changes (≥50 chromosomes).³
- Approval of CPX-351 was largely based on the primary analysis of patients who achieved CR or CRi with either 1 or 2 induction cycles with CPX-351 versus 7+3 (P=0.002).⁴

Methods

- The current analysis was conducted to further evaluate the impact of CPX-351 treatment on outcomes in patients who achieved CR or CRi but did not subsequently undergo HCT.

Objectives

- The primary exploratory objective of this phase 3 study was to evaluate the subgroup of patients who achieved CR or CRi with either 1 or 2 induction cycles with CPX-351 versus 7+3 who did not undergo HCT.

Results

- Of the 213 patients enrolled in the study, 146/213 (68%) patients with ≥20% blasts in peripheral blood at screening had a higher rate of patients undergoing hematopoietic cell transplantation.
- The longer median OS in this subgroup of patients who achieved remission was generally similar to that of conventional 7+3 (28.5 vs 29 months; HR = 0.57 [95% CI: 0.31, 1.03]; n=25/110).
- The median OS was longer with CPX-351 versus 7+3 among patients who achieved CR or CRi but did not undergo HCT.

Conclusions

- CPX-351 improved median OS versus 7+3 in the subgroup of patients who achieved CR or CRi but did not undergo HCT, suggesting a benefit with CPX-351 treatment over patients who did not subsequently undergo HCT.
- The longer median OS in the subgroup of patients who achieved CR or CRi with CPX-351 versus conventional 7+3 suggests potentially deeper responses may be achieved with CPX-351 treatment.
- The safety profile of CPX-351 in this subgroup was consistent with that of the overall study population and the known safety profile of 7+3.