Impact of Complete Remission on Overall Survival in Patients With Refractory/Relapsed Acute Myeloid Leukemia Treated With Vosaroxin Plus Cytarabine or Placebo Plus Cytarabine: Responder Analysis for the Phase 3 VALOR Trial

Harry P. Erba, MD, PhD; Farhad Ravandi, MD; Ellen K. Ritchie, MD; Hamid Sayar, MD; Jeffrey E. Lancet, MD; Stephen A. Strickland, MD; Gary J. Schiller, MD; Jennifer A. Smith, PhD; Renee Ward, MD, PhD; Robert K. Stewart, MD
Division of Hematology and Oncology, University of Alabama, Birmingham, AL; University of Texas MD Anderson Cancer Center, Houston, TX; Weill Cornell Medical Center, New York, NY; Yudapana University Cancer Center, Indianapolis, IN; Winship Cancer Center, University of Florida, Tampa, FL; Stanford-B Lanphier Cancer Center, Nashville, TN; University of California, Los Angeles, CA; Southwest Oncology Group, Chicago, IL; Southwest Oncology Group, Dallas, TX; Medical University of South Carolina, Charleston, SC

BACKGROUND

- Vosaroxin is a potent topoisomerase I inhibitor that stimulates DNA and RNA transcription (1). Vosaroxin is a topoisomerase I inhibitor that stimulates DNA and RNA transcription (1). Vosaroxin is a topoisomerase I inhibitor that stimulates DNA and RNA transcription (1). Vosaroxin is a topoisomerase I inhibitor that stimulates DNA and RNA transcription (1).

- In the phase 3 VALOR study, vosaroxin plus cytarabine prolonged overall survival in patients with refractory or relapsed AML compared with placebo plus cytarabine (HR: 0.80, 95% CI: 0.66–0.97; P = 0.024). (2–4)

- In this exploratory analysis of the VALOR data set, we examined the impact of achieving CR (versus not achieving CR) on the overall survival (OS) in patients enrolled in the phase 3 VALOR study (2–4). (5)

METHODS

- For the phase 3 VALOR study, patients were randomized 2:1 to receive vosaroxin/cytarabine (vos/Cyt; n = 356) or placebo/cytarabine (pla/Cyt; n = 285) and were stratified by baseline factors predictive of CR (3).

- The impact of CR on OS in the vosaroxin/cytarabine arm was also compared using a Cox proportional hazards model.

RESULTS

Complete Remission Rates in Patients Alive at 60 Days

- In the phase 3 VALOR study (2–4), baseline characteristics of the intent-to-treat population are summarized in Table 1.

- The impact of CR status at 60 days on OS was also analyzed using a Cox proportional hazards model.

- Table 2: Baseline Disease Characteristics (Overall VALOR Population)

- Table 3: Median OS by CR Status at Day 60 in Patients With R/R AML Treated With Vosaroxin/Cytarabine or Placebo/Cytarabine

CONCLUSIONS

- These exploratory analyses demonstrate that the survival benefit observed with vosaroxin/cytarabine versus placebo/cytarabine can be attributed to the increase in CRs produced with the addition of vosaroxin.

- Patients with CR lasting ≤120 days were neither treated nor compared with patients treated with vosaroxin/cytarabine plus placebo/cytarabine.

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REFERENCES