Voreloxin has been evaluated in a Phase 1 study in relapsed/refractory AML (Lancet ASH 2009).

**Conclusions:** Current results of REVEAL-1 suggest that voreloxin warrants development as a promising therapy for poor risk AML with multiple risk factors in the dose optimization study. REVEAL-1.

**Relevant Points:**
- 35 patients have been enrolled to date.
- Median age was 75 years (range 61-89).
- 75% of patients have an intermediate or unfavorable cytogenetics.
- 55% of patients have a history of and prior treatment for AHD allowed.
- Eligibility: newly diagnosed AML (de novo and 1 additional adverse risk factor [age ≥ 60 years, history of and prior treatment for AHD allowed].
- PK were evaluated in a patient subset in cycle 1.
- Final CR + CRp rate was 41% for Schedule A, 29% for; 10% for.
- Median duration of remission and count recovery of 19 evaluable patients have been observed thus far.
- Fifteen patients survived >6 months with an additional 6 surviving but who have been on-study for >6 months.

**Major Exclusion Criteria:**
- Previous history of chemotherapy in 19 evaluable patients.
- History of and prior treatment for AHD allowed.
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