THE EFFECT OF AZACITIDINE ON HEALTH-RELATED QUALITY OF LIFE (HRQL) IN OLDER PATIENTS WITH NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML): RESULTS FROM THE AZA-AML-001 TRIAL

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Background

Older patients (pts) with AML generally have a poor prognosis. While treatment (Tx) may extend overall survival (OS) for pts with AML, it may also cause significant toxicity and impairment of HRQL (Cheng, *Leukemia*, 2014). In the large, international, phase 3 AZA-AML-001 study, median OS for older pts with AML treated with azacitidine (AZA) was 10.4 months vs. 6.5 months for pts who received conventional care regimens (CCR; HR=0.85; p=0.1009) (Dombret, EHA, 2014). HRQL was a prespecified secondary endpoint of the study.

Aims

To evaluate changes in HRQL during Tx among pts in AZA-AML-001.

Methods

Pts were aged ≥65 years with newly diagnosed *de novo* or secondary AML (>30% bone marrow blasts). Before randomization, pts were preselected to receive 1 of 3 CCR per investigator choice: induction chemotherapy, low-dose cytarabine (LDC), or best supportive care only. Pts were then randomized to AZA or CCR, in which case, they received their preselected Tx. Most pts (n=312, 64%) were preselected to receive LDC. HRQL was assessed by EORTC QLQ-C30 questionnaire at baseline, day 1 of every other Tx cycle, and at the end-of-study visit, which occurred at different time points for individual pts. Analyses included only pts who completed the baseline and at least 1 post-baseline HRQL assessment. An HRQL-specific statistical analysis plan (SAP) was finalized before database lock. HRQL changes were evaluated prospectively for the AZA and CCR cohorts, and *post hoc* for the pt subgroup preselected to LDC who received AZA or LDC. Four of the 15 QLQ-30 domains were prespecified in the SAP as most relevant: Fatigue (primary), Global Health Status/QoL, Physical Functioning, and Dyspnea (secondary). HRQL was evaluated through cycle 9 (~32 to 34 weeks) due to subsequent small cohort sizes. A prespecified 10-point minimally important difference (MID) threshold represents meaningful change.

Mean Changes from Baseline EORTC QLQ-30 Domain Scores