Abstract: P571

Title: REAL-WORLD USE OF ORAL-AZACITIDINE AS MAINTENANCE THERAPY FOR ACUTE MYELOID LEUKEMIA IN REMISSION: CHARACTERISTICS AND OUTCOMES OF A FRENCH PATIENT POPULATION

Abstract Type: Poster Presentation

Topic: Acute myeloid leukemia - Clinical

Background:

Induction therapy for patients with acute myeloid leukemia (AML) aims to induce complete remission (CR). While patients achieve remission after induction treatment with or without consolidation therapy, most of them will eventually relapse. The goal of maintenance therapy in AML is to decrease the likelihood of disease relapse and prolong overall survival (OS). In the QUAZAR AML-001 study, maintenance therapy with oral azacitidine (Oral-AZA) was associated with significantly longer OS and relapse-free survival (RFS) compared with placebo among patients with AML in first remission after intensive chemotherapy.

Aims:

This non-interventional, retrospective, multicentric, national study in France aims to describe real-world clinical outcomes in patients with AML who received maintenance therapy with Oral-AZA while in remission after frontline treatment.

Methods:

Patients initiated Oral-AZA maintenance either during the Early Access Program (EAP) in France implemented from 29 January 2021 to 13 July 2022 or in the 6-month post-EAP period (14 July 2022 to 14 January 2023).

Results:

The first analysis set included 50 patients from 13 sites. Patients had a median (range) age of 69 (30-89) years at Oral-AZA initiation, 28 (56%) were male. ECOG performance status at Oral-AZA initiation was evaluated on 28 patients of whom 25 had an ECOG 0-1. At Oral-AZA initiation, 24 patients had been assessed for MRD status, which was negative for 22 of them. Molecular aberrations were detected in a proportion of patients and included: NPM1 (44%), FLT3-ITD (12%), FLT3-TKD (8%), CEBPA (8%), IDH2 (8%), SRSF2 (8%) and ASXL1 (4%). Most common frontline treatments prior to Oral-AZA initiation were standard 7+3 (cytarabine + idarubicin/daunorubicin) for 40% of patients, combinations of 7+3 with other agents including (but not limited to) midostaurin (16%) or lomustine (16%), CPX-351 (6%) and VEN-AZA (6%). Most patients (78%) have received consolidation treatment and the median (range) number of consolidation cycles prior to Oral-AZA initiation was 3 (1-6). The median RFS (95% confidence interval [CI]) from Oral-AZA initiation was 20.2 (12.7, NR) months with RFS rates of 69.3% (54.4, 80.2) at 12 months (Figure). Median OS (95% CI) from Oral-AZA initiation was not reached with OS rates of 84% (70.5, 91.6) at 12 months (Figure). The median (95% CI) time to Oral-AZA treatment discontinuation was 15.4 (6.9, 16.5) months, with 51.9% (37.3, 64.6) remaining on treatment at 12 months. Safety results were consistent with the known safety profile of Oral-AZA, and no major safety signals were reported. The final analysis of a larger population is ongoing and will be provided at the time of the presentation.

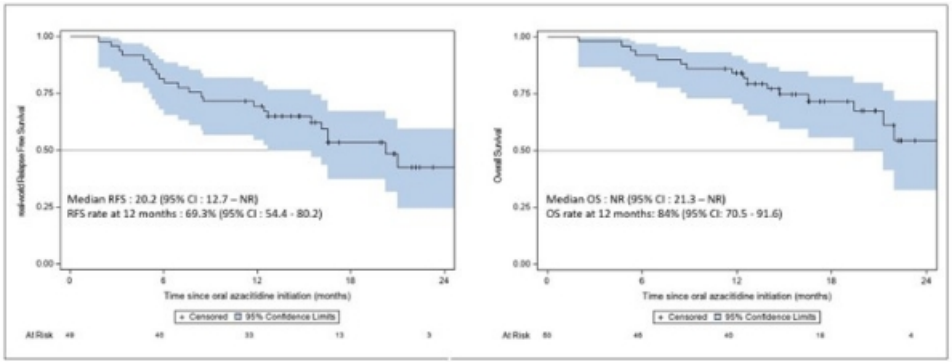

Figure. Kaplan Meier relapse free survival and overall survival from the time of Oral-AZA initiation.

Summary/Conclusion:

This is the first real-world data analysis of characteristics and outcomes from patients with AML treated with Oral-AZA maintenance in France. These results corroborate the survival benefits observed with Oral-AZA in the QUAZAR AML-001 study and support the broad use of this maintenance therapy in patients with AML who do not proceed to transplant at remission.

Keywords: Maintenance, Real world data, AML, Chemotherapy