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Context: Ivosidenib (IVO; AG-120) is an oral, targeted inhibitor of mutant isocitrate dehydrogenase 1 (mIDH1) that is being evaluated in a phase 1 dose escalation and expansion study of mIDH1 advanced hematologic malignancies (NCT02074839). **Objective:** To report updated efficacy and safety data from all patients with relapsed/refractory acute myeloid leukemia (R/R AML) receiving IVO 500 mg once daily (QD). **Methods:** The primary efficacy endpoint was the CR+CRh rate (complete remission [CR] according to modified IWG 2003 criteria plus CR with partial hematologic recovery [CRh]). CRh was defined as absolute neutrophil count $>0.5 \times 10^9$/L and platelet count $>50 \times 10^9$/L. The overall response rate (ORR) comprised CR, CR with incomplete hematologic or platelet recovery, partial response, and morphologic leukemia-free state. The data cutoff date for this analysis was Nov 10, 2017. **Results:** A total of 258 patients were treated with IVO. Among 179 R/R AML patients who received IVO 500 mg QD, 17 (9.5%) remained on treatment at data cutoff. In R/R AML patients, the CR+CRh rate was 31.8% (95% CI: 25.1%, 39.2%), including CR in 24.0% (95% CI: 18.0%, 31.0%). Median duration of CR+CRh was 8.2 months (95% CI: 5.6, 12.0), and median duration of CR was 10.1 months (95% CI: 6.5, 22.2). The ORR was 41.9% (95% CI: 34.6%, 49.5%). Treatment was well tolerated; the most common adverse events (AEs) of any grade, irrespective of causality and occurring in ≥25% of 179 R/R AML patients were diarrhea (33.5%), leukocytosis (31.3%), nausea (31.3%), febrile neutropenia (29.1%), fatigue (28.5%), and electrocardiogram QT prolonged (25.7%). The majority of these AEs were grade 1−2 and unrelated to treatment. IDH differentiation syndrome (IDH-DS) was reported in 19 of 179 (10.6%) patients, including grade ≥3 IDH-DS in 9 (5.0%); study drug was held owing to IDH-DS in 6 patients (3.4%), and no instances of IDH-DS led to dose reduction, permanent treatment discontinuation, or death. Updated mutation clearance results will be provided. **Conclusions:** In a high-risk, molecularly defined R/R AML patient population, IVO induced durable remissions and was well tolerated. Studies in previously untreated AML populations are ongoing.

Keywords: acute myeloid leukemia, AG-120, ivosidenib, clinical trial, relapsed AML

AML-232

Pre-Treatment Risk Assessment for Elderly Patients with Acute Myeloid Leukemia

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Context: The treatment of AML in older adults is limited by the high mortality related with induction chemotherapy; however, those who tolerate an intensive treatment will have better outcomes; therefore, selecting this group of patients through the use of functionality scales is a fundamental part of the initial therapeutic approach. Risk assessment scales have been designed and validated by other authors; in our country they have not been routinely used until now. **Objective:** To describe 8-week treatment related and 1-year mortality in AML patients, older than 60 years, after selecting treatment based on functionality risk scores (FRS), at two hospitals in Bogotá. **Design:** An observational study was performed, analyzing early mortality in two cohorts; a retrospective, including patients treated from 2010-2015 and a prospective one, from 2015 to 2018, in which the treatment was selected according FRS (SPPB, CCI and MD Anderson Predictive Score). **Setting:** Patients were treated in two university hospitals in Bogotá, Colombia. **Patients:** AML patients older than 60 years; acute promyelocytic leukemia patients were excluded. **Interventions:** FRS were assessed at diagnosis, high risk patients received supportive care, intermediate risk received 5-Azacitidine or low dose ARA-C, low risk patient were