Venetoclax is being codeveloped by AbbVie and Genentech, a member of the Roche Group.

Dosing

- **Cycle 1:** Venetoclax D1 (100 mg); D2 (200 mg); D3 (400 mg); D4-28 (600 mg) PO QD
  LDAC 20 mg/m² SQ on days 1-10 (28 day cycle)
- Venetoclax (600 mg) PO QD on days 1-28 plus LDAC 20 mg/m² SQ QD on days 1-10 (28 day cycle)
- Placebo PO QD on days 1-28 plus LDAC 20 mg/m² SQ QD on days 1-10 (28 day cycle)

**Key Inclusion Criteria**

- Previously untreated AML
- ≥ 18 yrs of age
- Ineligible for intensive chemotherapy
- ECOG PS 0-2 for subjects ≥ 75 yrs of age; 0-3 for subjects 18-74 yrs of age

**Key Exclusion Criteria**

- Any prior treatment for AML, with the exception of hydroxyurea, allowed through the first cycle of study treatment
- Prior MPN • APL • CNS involvement
  *Prior treatment for Myelodysplastic Syndrome is allowed except for use of cytarabine

**Endpoints**

- **Primary**
  - OS
- **Secondary**
  - Composite CRR (CR + CRi), EFS, CCRR by initiation of Cycle 2, fatigue reduction based on PROMIS F-SF 7a
- **Exploratory**
  - Predictive biomarker analysis, EORTC QLQ-C30, EQ-5D-5L

Venetoclax is being investigated for indications that have not been approved by Regulatory Agencies. Safety and Efficacy have not been established in unapproved indications.

AML, acute myeloid leukemia; APL, acute promyelocytic leukemia; CNS, central nervous system; CCRR, composite complete remission rate; CR, complete remission; CRi, complete remission with incomplete blood count recovery; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; HA, hydroxyurea; LDAC, low-dose cytarabine; MDS, myelodysplastic syndromes; MPN, myeloproliferative neoplasm; OS, overall survival; PO, taken orally; SC, subcutaneous.


To learn more about these studies, please visit [https://ClinicalTrials.gov](https://ClinicalTrials.gov) or email abbvieclinicaltrials@abbvie.com