Phase 1b MDS (M15-522)
Study Design and Endpoints

A Study Evaluating the Safety and PK of Venetoclax as a Single Agent and in Combination With Azacitidine in Subjects With Higher-Risk Myelodysplastic Syndromes (MDS) After Hypomethylating Agent-Failure

**Key Inclusion Criteria**
- Age ≥ 18 years
- Failure on HMA for 1L treatment for higher risk MDS
- Bone marrow blasts ≥ 5% and < 20%
- ECOG PS 0-2

**Key Exclusion Criteria**
- Received more than 1 prior therapy for MDS
- Therapy-related MDS
- MDS evolved from MPN
- Received prior BH3 mimic

**Endpoints**
- Primary: Safety, PK, RP2D
- Secondary: ORR, CR, HI, DOR, OS, PFS

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

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