Phase 1b MDS (M15-531)
Study Design and Endpoints
A Study Evaluating the Safety and PK of Venetoclax in Combination With Azacitidine in Subjects With Treatment-Naïve Higher-Risk Myelodysplastic Syndromes (MDS)

Key Inclusion Criteria
- Age ≥ 18 years
- Untreated higher risk de novo MDS (IPSS risk categories Int-2 or High)
- Bone marrow blasts ≥ 5% and < 20%
- ECOG PS 0-2
- Not a candidate for intensive chemotherapy or allogeneic HSCT

Key Exclusion Criteria
- Received prior therapy for MDS
- Therapy-related MDS
- Received prior BH3 mimetic
- MDS evolved from MPN
- Received allogeneic HSCT or solid organ transplantation

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