Phase 1/2 Multiple Myeloma (M15-654)

A Phase 1/2, Multicenter, Dose-Escalation and Expansion Study of Combination Therapy with Venetoclax, Daratumumab and Dexamethasone (with and without Bortezomib) in Subjects with Relapsed or Refractory Multiple Myeloma

Venetoclax is being codeveloped by AbbVie and Genentech, a member of the Roche Group, and Onyx Therapeutics, Inc., a wholly owned subsidiary of Amgen Inc.

Key Endpoints

Primary
- Cohort 1: VenDd in t(11;14) positive R/R multiple myeloma
  - Dose escalation: Safety and tolerability
  - Randomized, placebo-controlled expansion: Response rates (ORR, including PR or better)
  - VGPR or better
- Cohort 2: VenDVd in R/R multiple myeloma
  - Dose escalation: Safety and tolerability
  - Single-arm, open-label expansion: CR rates or better (sCR, CR)

Secondary
- Safety profile (VenDd, VenDVd)
- Pharmacokinetics of Ven, D, and V given as VenDd or VenDVd
- Time to event: PFS, DOR, TTP
- To explore MRD in the bone marrow by NGS

Inclusion Criteria

- ECOG PS ≤ 2
- Venetoclax and daratumumab naive
- R/R Multiple Myeloma as described in schema above

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

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

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