Phase 3 Multiple Myeloma (M13-494)

A phase 3, multicenter, randomized, open label study of venetoclax and dexamethasone compared with pomalidomide and dexamethasone in subjects with t(11;14) positive-relapsed or refractory multiple myeloma.

Key Inclusion Criteria
- t(11;14)-positive R/R multiple myeloma
- ≥2 prior lines of therapy
- ECOG PS ≤2
- Documented disease progression on or within 60 days after completion of their last therapy
- Prior exposure to lenalidomide and a PI (at least 2 consecutive cycles each)
- Refractory to lenalidomide
- Venetoclax and pomalidomide naive

Stratification Factors
- Age at randomization (< 65 vs ≥ 65)
- Prior lines of therapy (2-3 vs ≥4)
- ISS Stage (I vs II vs III)

Dosing
- Venetoclax (800 mg) PO QD D1-28 (for each 28-day cycle)
- Pomalidomide 4 mg PO QD D1-21 (for each 28-day cycle)
- Dexamethasone 40 mg (20 mg for patients ≥75 years old) once weekly on D1, D8, D15, and D22 (for each 28 day cycle)

Key Endpoints Criteria

Primary
- PFS based on IRC review

Secondary
- Response rates (ORR, VGPR or better)
- Time to event: OS, DOR, and TTP
- MRD rate
- Pharmacokinetics
- Safety
- PROs: Worst Pain (BPI-SF), Fatigue (PROMIS), Physical Functioning (EORTC QLQ-C30), and Global Health Status (EORTC QLQ-C30)

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.

The anticipated trial start date is October 2018.

To learn more about our pipeline, please visit www.abbvie.com/oncology

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