Phase 2 Multiple Myeloma (M13-367): Expansion, Study Design and Endpoints

A phase 2 expansion study of venetoclax in combination with dexamethasone in patients with t(11;14)-positive relapsed or refractory multiple myeloma

**Key Inclusion Criteria**
- $t(11;14)$-positive R/R MM
- PD on or within 60 days after completion of last therapy
- Received ≥ 3 lines of therapy, including an IMiD (lenalidomide, pomalidomide), a PI (bortezomib, carfilzomib, ixazomib) and daratumumab, glucocorticoids, given alone or in combination

**Key Endpoints**
- **Primary:** Response rates (ORR, VGPR or better)
- **Secondary:**
  - Time to event: OS, PFS, DOR, TTP, and TTR
  - Safety
  - Pharmacokinetics

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.