

A Phase 3 Study of PF-06863135 Monotherapy and PF-06863135 + Daratumumab Versus Daratumumab + Pomalidomide + Dexamethasone in Participants With Relapsed/Refractory Multiple Myeloma

MagnetisMM-5 is an open-label, 3-arm, multicenter, randomized Phase 3 study to evaluate the efficacy and safety of PF-06863135 monotherapy and PF-06863135 + daratumumab versus daratumumab + pomalidomide + dexamethasone in participants with relapsed/refractory multiple myeloma who have received at least 1 prior line of therapy including lenalidomide and a proteasome inhibitor (PI)

Part 1 of the study will assess the safety and activity of different doses of PF-06863135 in combination with daratumumab. Part 2 will compare the safety and activity of (1) PF-06863135 alone compared to daratumumab, pomalidomide, and dexamethasone, and (2) PF-06863135 plus daratumumab compared to daratumumab, pomalidomide, and dexamethasone.

PF-06863135 is an investigational compound. These are not the complete inclusion/exclusion criteria. This information is current as of January 2022.

KEY INCLUSION CRITERIA:

- Multiple myeloma (MM) diagnosis as defined according to International Myeloma Working Group (IMWG)
- Age ≥18 years
- Prior anti-MM therapy including treatment with lenalidomide and a PI
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2
- Adequate renal, hepatic, cardiac, and bone marrow function

KEY EXCLUSION CRITERIA:

- Smoldering MM
- Plasma cell leukemia
- Amyloidosis
- Polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes (POEMS) syndrome
- Stem cell transplant within 12 weeks prior to enrollment
- Previous treatment with a B-cell maturation antigen (BCMA)-directed therapy
- Anti-CD38-directed therapy within 6 months preceding the first dose of treatment in this study
- Active, uncontrolled bacterial, fungal or viral infection

PATIENT POPULATION (N=476):

- MM
- Prior anti-MM therapy including lenalidomide and a PI
- No prior BCMA-directed therapy
- No prior anti-CD38-directed therapy within 6 months of study entry

PART 2 RANDOMIZATION

PF-06863135 monotherapy

PF-06863135 + daratumumab

daratumumab + pomalidomide + dexamethasone

PRIMARY ENDPOINT:

- Progression-free survival (part 2)

KEY SECONDARY ENDPOINTS:

- Overall survival
- Objective response rate/complete response rate
- Duration of response
- Time to response
- Minimal residual disease (MRD) negativity rate/sustained MRD negativity rate
- Progression-free survival (PFS) on next-line treatment
- Safety
- Pharmacokinetics
- Immunogenicity
- Health-related quality of life (HRQoL)

Learn more at [ClinicalTrials.gov](https://clinicaltrials.gov)
NCT05020236