

A Phase 1/2 Study to Evaluate a Two Step-up Priming Dose Regimen and Longer Dosing Intervals of Investigational Elranatamab (PF-06863135) Monotherapy in Participants with Relapsed or Refractory Multiple Myeloma (MM)^{1,2}

MagnetisMM-9 is an open-label, multicenter, non-randomized Phase 1/2 study of elranatamab monotherapy in participants with MM who are refractory to at least one proteasome inhibitor (PI), one immunomodulatory drug (IMiD), and one anti-CD38 monoclonal antibody (mAb).

Elranatamab is an investigational compound. These are not the complete inclusion/exclusion criteria. This information is current as of October 2021.

KEY INCLUSION CRITERIA:

- MM diagnosis as defined according to International Myeloma Working Group (IMWG)
- Age ≥18 years
- Refractory to ≥1 IMiD, ≥1 PI, and ≥1 anti-CD38 mAb
- Relapsed or refractory to last anti-MM regimen
- Eastern Cooperative Oncology Group (ECOG) Performance Status ≤1
- Adequate renal, hepatic, cardiac, and bone marrow function

KEY EXCLUSION CRITERIA:

- Smoldering MM
- Plasma cell leukemia
- Amyloidosis
- Active and clinically significant bacterial, fungal, or viral infection
- Polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes (POEMS) syndrome
- Stem cell transplant within 12 weeks prior to enrollment
- Previous treatment with anti-B-cell maturation antigen (BCMA) bispecific antibody

Patient Population (N=76)

PART 1

elranatamab monotherapy
subcutaneous (SC)
2 step-up priming doses + full dose

PART 2

Dose Exploration

elranatamab monotherapy SC
2 step-up priming doses + alternative
dosing regimen

PRIMARY ENDPOINT:

- Grade ≥2 cytokine release syndrome (CRS) rate during Cycle 1

KEY SECONDARY ENDPOINTS:

- Incidence of dose-limiting toxicity during Cycle 2 for Part 2 only
- Safety
- Objective response rate
- Duration of response
- Progression-free survival
- Overall survival
- Minimal residual disease (MRD) negativity rate
- Pharmacokinetics
- Immunogenicity

Learn more at ClinicalTrials.gov
NCT05014412