Protocol Title: BiTE (C1071001): A Phase I, Open-Label Study to Evaluate the Safety, Pharmacokinetic, Pharmacodynamic, and Clinical Activity of PF-06863135, a B-Cell Maturation Antigen (BCMA) – CD3 Bispecific Antibody, in Patients with Relapsed / Refractory Advanced Multiple Myeloma (MM)

Target Population: Relapsed / Refractory Advanced Multiple Myeloma (MM)

Summary: C1071001 is a Phase 1, open label, multi dose, multi-center, dose escalation, safety, pharmacokinetic and pharmacodynamic study of PF-06863135 in adult patients with advanced Multiple Myeloma who have relapsed from or are refractory to standard therapy. This two-part study will assess the safety and tolerability of increasing dose levels of PF-06863135 in Part 1 and establish recommended Phase 2 dose (RP2D) in Part 2.

Key Inclusion Criteria:
- Relapsed / Refractory Advanced Multiple Myeloma
- Performance Status of 0- 2 (unless due to bone pain)
- Adequate bone marrow, kidney and liver function

Key Exclusion Criteria:
- History of active autoimmune disorders
- Active and clinically significant bacterial, fungal, or viral infection
- Major surgery within 4 Weeks of study treatment start
- Radiation therapy within 2 Weeks of study treatment start
- Less than 30 Days since last dose of anti-CD38 therapy, Elotuzumab or other anti-CD319 therapy or less than 5 half-lives since last dose of previous systemic therapy
- Stem cell transplant (autologous or allogeneic) within 100 Days of study treatment start

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03269136