Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	Étude ouverte de phase I visant à évaluer l'innocuité, la pharmacocinétique, la pharmacodynamique et l'activité clinique du PF-06863135, un anticorps bispécifique ciblant un antigène de maturation des cellules B (BCMA)-CD3, en tant qu'agent unique et en association avec des agents immunomodulateurs chez des patients atteints d'un myélome multiple (MM) avancé récidivant/réfractaire
Protocole ID	C1071001
ClinicalTrials.gov ID	NCT03269136
Type(s) de cancer	Myélome
Phase	Phase I
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	PF-06863135 seul et en association avec des agents immunomodulateurs
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Chaim Shustik Dr Michael Sebag
Coordonnateur	Nancy Renouf 514-934-1934 poste 35718
Statut	Actif en recrutement
But étude	Study C1071001 is a Phase 1, open label, multi dose, multi center, dose escalation, safety, pharmacokinetic (PK) 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 the recommended Phase 2 dose (RP2D) in Part 2.
Critères d'éligibilité	• Relapsed/refractory multiple myeloma • Progressed or are intolerant of established therapies including proteasome inhibitor, immunomodulatory drug, and anti-CD38 antibody • Performance Status of 0- 2 (unless due to bone pain) • Adequate bone marrow, hematological, kidney and liver function • Resolved acute effects of any prior therapy to baseline severity • Not pregnant
Critères d'exclusion	• Recent history of other malignancies • History of active autoimmune disorders • Any form of primary immunodeficiency • Active and clinically significant bacterial, fungal, or viral infection • Evidence of active mucosal or internal bleeding • History of severe immune-mediated adverse event with prior immunomodulatory treatment • Major surgery within 4 weeks of study treatment start • Radiation therapy within 2 weeks of study treatment start • History of stem cell transplant (autologous or allogeneic) within 100 days prior to study enrollment

- Donor Lymphocyte Infusion (DLI) within 30 days prior to study entry
- Less than 30 days since last dose of antibody based therapies or less than 5 half-lives since last dose of previous therapy
- Requirement for systemic immune suppressive medication
- Current requirement for chronic blood product support