Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	A Phase 1b/2 Open-Label, Multicenter Study to Evaluate the Safety and Efficacy of TAK-981 in Combination With Monoclonal Antibodies in Adult Patients With Relapsed and/or Refractory Multiple Myeloma
Protocole ID	TAK-981-1503
ClinicalTrials.gov ID	NCT04776018
Type(s) de cancer	Myélome
Phase	Phase I-II
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	TAK-981 avec mezagitamab ou TAK-981 avec daratumumab et hyaluronidase-fihj
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	
Investigateur principal	Dr Richard Leblanc
Coordonnateur	Marie-Pier Lecours-Cyr 514-252-3400 poste 5037
Statut	Fermé
Date d'activation	08-11-2022
But étude	TAK-981 is being tested in combination with anti-CD38 monoclonal antibodies (mAbs) to treat participants who have relapsed or refractory multiple myeloma (RRMM). The main aims of the study are to evaluate the safety and efficacy of TAK-981 in combination with anti-CD38 (mAbs) and to determine the recommended Phase 2 dose (RP2D). Participants will be on this combination treatment for 28-day cycles. They will continue with this treatment until disease progression or unacceptable toxicity.

Critères d'éligibilité	• Participants must have RRMM with measurable disease. Measurable disease is defined as one of the following:
	  • Serum M-protein ≥0.5 g/dL (≥5 g/L).
	  • Urine M-protein ≥200 mg/24 hours.
	  • In participants without measurable M-protein in serum protein electrophoresis (SPEP) or urine protein electrophoresis (UPEP), a serum free light chain (FLC) assay result with involved FLC level ≥10 mg/dL (≥100 mg/L), provided serum FLC ratio is abnormal.
	• Has undergone stem cell transplant or is considered transplant ineligible.
	• Has failed at least 3 prior lines of anti-myeloma treatments and is either refractory, or intolerant to at least 1 immunomodulatory drug (IMiD); (ie, lenalidomide or pomalidomide [thalidomide excluded]), at least 1 proteasome inhibitor (ie, bortezomib, ixazomib or carfilzomib), and refractory to at least 1 anti-CD38 antibody and who have demonstrated disease progression with the last therapy.
	• Have a performance status of 0-2 on the Eastern Cooperative Oncology Group (ECOG) Performance Scale.
	• Have recovered to Grade 1 or baseline from all toxicity associated with previous therapy or have the toxicity established as sequela.

Critères d'exclusion	• Received treatment with systemic anticancer treatments within 14 days before the first dose of study drug. • Current participation in another interventional study, including other clinical trials with investigational agents (including investigational vaccines or investigational medical device for disease under study) within 4 weeks of the first dose of TAK-981 and throughout the duration of this trial. • Prior radiation therapy within 14 days of the first dose of TAK-981. • Major surgery within 4 weeks before C1D1. participants should be fully recovered from any surgically related complications. • Plasmapheresis within 28 days of randomization. • Diagnosis of primary amyloidosis, Waldenström's disease, monoclonal gammopathy of undetermined significance or smoldering multiple myeloma (SMM), plasma cell leukemia POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes), myelodysplastic syndrome, or myeloproliferative syndrome. • With disease where the only measurable parameter is plasmacytoma. • Second malignancy within the previous 3 years, except treated basal cell or localized squamous skin carcinomas, localized prostate cancer, cervical carcinoma in situ, resected colorectal adenomatous polyps, breast cancer in situ, or other malignancy for which the participant is not on active anticancer therapy. • Prior treatment with more than 1 anti-CD38 antibody. • Requires the use of drugs known to prolong the corrected QT interval (QTc) (during Phase 1b only). • History of QT interval with Fridericia's correction (QTcF) >480 ms. • History of human immunodeficiency virus (HIV), hepatitis B virus, or hepatitis C infection. • Systemic infection requiring systemic antibiotic therapy. • Active or history pneumonitis. • Receipt of any live vaccine (eg, varicella, pneumococcus) within 4 weeks of initiation of study drug. • Receiving strong or moderate Cytochrome P450 (CYP) 3A4/5 inhibitors or inducers. • History of unstable cardiac comorbidities in the following 6 months.