Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Étude ouverte de phase I/II à doses croissantes menée pour la première fois chez l'humain, portant sur le teclistamab, un anticorps BCMA humanisé x bispécifique CD3, chez des sujets atteints d'un myélome multiple récidivant ou réfractaire
Protocole ID	64007957MMY1001
ClinicalTrials.gov ID	NCT04557098
Type(s) de cancer	Myélome
Phase	Phase I-II
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	Teclistamab
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Chaim Shustik Dr Michael Sebag
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Statut	Actif en recrutement
But étude	The study will be conducted in 2 parts, separately for IV and SC administration: dose escalation (Part 1) and dose expansion (Part 2). It will evaluate safety, tolerability, pharmacokinetics and preliminary antitumor activity of Teclistamab administered to adult participants with relapsed or refractory multiple myeloma. The overall safety of the study drug will be assessed by physical examinations, Eastern Cooperative Oncology Group performance status, laboratory tests, vital signs, electrocardiograms, adverse event monitoring, and concomitant medication usage. Disease evaluations will include peripheral blood and bone marrow assessments at screening (performed within 28 days) and to confirm stringent complete response (sCR), complete response (CR), or relapse from CR. The end of study (study completion) is defined as 2 years after the last participant in Part 3 has received his or her initial dose of teclistamab. Study record NCT04557098 is Phase 2 part of this study and study record NCT03145181 is Phase 1 part of this study.
Critères d'éligibilité	• Documented diagnosis of multiple myeloma according to IMWG diagnostic criteria • Eastern Cooperative Oncology Group (ECOG) Performance Status score of 0 or 1 • Measurable disease: Multiple myeloma must be measurable by central laboratory assessment • Women of childbearing potential must have a negative pregnancy test at screening • Willing and able to adhere to the prohibitions and restrictions specified in this protocol • Cohort A: received at least 3 prior MM treatment lines of therapy Prior therapy must include an IMiD, PI, and anti-CD38 monoclonal antibody; Cohort B: received at least 4 prior MM treatment lines of therapies and whose disease is penta-refractory to at least 2 PIs, at least 2 IMiDs, and an anti-CD38 monoclonal antibody; Cohort C: received >= 3 prior lines of therapy that included a PI, an IMiD, an anti-CD38 monoclonal antibody, and an anti-B cell maturation antigen (BCMA) treatment (with CART-T cells or an antibody drug conjugate (ADC)

Critères d'exclusion	• Plasma cell leukemia, Waldenström's macroglobulinemia, POEMS syndrome, or primary amyloid light-chain amyloidosis • The following medical conditions: Pulmonary compromise requiring supplemental oxygen use to maintain adequate oxygenation, human immunodeficiency virus (HIV) infection, hepatitis B or C infection, stroke or seizure less than or equal to (<=) 6 m, autoimmune disease, uncontrolled systemic infection, cardiac conditions (Myocardial Infarction <= 6 m, stage III-IV congestive heart failure, etc) • Received any therapy that is targeted to BCMA, with the exception of Cohort C in Part 3 • Prior antitumor therapy, within 21 days (PI or radiotherapy within 14 days, IMiDs within 7 days, Gene modified adoptive cell therapy within 3 months) prior to first dose of study drug • Toxicities from previous anticancer therapies that have not resolved to baseline or to <= grade 1 (except for alopecia or peripheral neuropathy) • Received a cumulative dose of corticosteroids equivalent to >=140 mg of prednisone within the 14-day period before the first dose of study drug (does not include pretreatment medication) • Known active central nervous system (CNS) involvement or exhibits clinical signs of meningeal involvement of multiple myeloma (MM) • Active malignancies with exceptions are: 1) Non-muscle invasive bladder cancer. 2) Skin cancer (non-melanoma or melanoma) treated within the last 24 months that is considered completely cured. 3) Noninvasive cervical cancer treated within the last 24 months that is considered completely cured. 4) Localized prostate cancer (N0M0) 5) Breast cancer: Adequately treated lobular carcinoma in situ or ductal carcinoma in situ, or history of localized breast cancer and receiving antihormonal agents and considered to have a very low risk of recurrence. 6) Malignancy that is considered cured with minimal risk of recurrence • Prior allogenic stem cell transplant <=6 months • Prior autologous stem cell transplant <=12 weeks • Live, attenuated vaccine within 4 weeks prior to the first dose of teclistamab