Essai Clinique

Généré le 07 mai 2025 à partir de

Titre	Étude multicentrique de phase Ib/IIa, ouverte et à doses croissantes visant à déterminer la dose maximale tolérée et à évaluer l'innocuité, la tolérabilité, la pharmacocinétique et l'efficacité du CC-220 en monothérapie et en association avec d'autres traitements chez des sujets atteints de myélome multiple
Protocole ID	CC-220-MM-001
ClinicalTrials.gov ID	NCT02773030
Type(s) de cancer	Myélome
Phase	Phase I-II
Type étude	Clinique
Médicament	CC-220 en monothérapie et en association avec d'autres traitements
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	Fermé
But étude	This is a multicenter, multi-country, open-label, Phase 1b/2a dose-escalation study consisting of two parts: dose escalation (Part 1) for CC-220 monotherapy, CC-220 in combination with DEX, CC-220 in combination with DEX and DARA, CC-220 in combination with DEX and BTZ and CC-220 in combination with DEX and CFZ; and the expansion of the RP2D (Part 2) for CC-220 in combination with DEX for Relapsed Refractory Multiple Myeloma and CC-220 in combination with DEX and BTZ for Newly Diagnosed Multiple Myeloma.
Critères d'éligibilité	All subjects in RRMM cohorts must have a documented diagnosis of Multiple Myeloma and have measurable disease defined as: 1. M-protein (serum and/or urine protein electrophoresis (sPEP or uPEP)): sPEP ≥0.5 g/dL or uPEP ≥200 mg/24 hours and/or 2. Light chain Multiple Myeloma without measurable disease in the serum or urine: serum immunoglobulin free light chain ≥ 10 mg/dL (100 mg/L) and abnormal serum immunoglobulin kappa lambda free light chain ratio 2. All subjects in RRMM cohorts must have documented disease progression on or within 60 days from the last dose of their last myeloma therapy. Subjects who had CAR T therapy as their last myeloma therapy must have documented disease progression. 3. Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1 or 2 3. Subject must have documented diagnosis with previously untreated symptomatic MM as defined by the criteria below (Rajkumar, 2016): MM diagnostic criteria; Clonal bone marrow plasma cells ≥ 10% or biopsy-proven bony or extramedullary plasmacytoma- Any one or more of the following myeloma defining events: • One or more of the following myeloma-related organ dysfunction (at least one of the following);• [C] Calcium elevation (serum calcium > 0.25 mmol/L [> 1 mg/dL] higher than the upper limit of laboratory normal or > 2.75 mmol/L [> 11 mg/dL])• [R] Renal insufficiency (serum creatinine > 2 mg/dl [> 177 µmol/L] or creatinine clearance < 40 ml/min) • [A] Anemia (hemoglobin < 10 g/dl or > 2 g/dL below the lower limit of laboratory

	normal) • [B] Bone lesions (lytic or osteopenic) one or more bone lesions on skeletal radiography, computed tomography (CT), or positron emission tomography (PET)/CT • One or more of the following biomarkers of malignancy: • Clonal bone marrow plasma cell percentage* ≥ 60% • Abnormal serum free light-chain (FLC) ratio ≥ 100 (involved kappa) or <0.01 (involved lambda) and involved FLC level must be ≥ 100 mg/L • >1 focal lesion detected by magnetic resonance imaging (MRI) (at least 5 mm in size) AND have measurable disease, as assessed by central laboratory, defined by any of the following:- Immunoglobulin (Ig)G myeloma: serum M-protein level ≥ 1.0 g/dL or urine M-protein level ≥ 200 mg/24 hours; or- IgA, IgM, IgD, or IgE multiple myeloma: serum M-protein level ≥ 0.5 g/dL or urine M-protein level ≥ 200 mg/24 hours; or- Light chain multiple myeloma without measurable disease in serum or urine: serum FLC ≥ 100 mg/L and abnormal kappa lambda (κ/λ) ratio 4. Subjects in Cohort J1 are not considered by the investigator as eligible for high-dose chemotherapy and autologous stem cell transplantation due to:- Age ≥65 years, OR - In subjects <65 years: presence of important comorbid condition(s) likely to have a negative impact on tolerability of high-dose chemotherapy with autologous stem cell transplantation.5. Subjects in Cohort J2 are considered by the investigator as eligible for high-dose chemotherapy and autologous stem cell transplantation according to the institution's criteria based on age, medical history, cardiac and pulmonary status, overall health and condition, co-morbid condition(s), physical examination, and laboratory data.
Critères d'exclusion	1. Subject has nonsecretory multiple myeloma 2. Subjects with Plasma Cell leukemia or amyloidosis 3. Any of the following laboratory abnormalities • Absolute neutrophil count (ANC) <1,000/µL • Platelet count < 75,000/µL for Part 1. For Part 2; platelet count < 75,000/µL for subjects in whom < 50% of bone marrow nucleated cells are plasma cells; otherwise platelet count < 50,000/µL (transfusions are not permitted to achieve minimum platelet counts • Corrected serum calcium >13.5 mg/dL (>3.4 mmol/L) • Serum glutamic oxaloacetic transaminase (SGOT)/aspartate aminotransferase (AST) or serum glutamic pyruvic transaminase (SGPT)/alanine aminotransferase (ALT)≥2.0 x upper limit of normal (ULN) • Serum total bilirubin and alkaline phosphatase >1.5 x ULN • Subjects with serious renal impairment creatinine clearance ([CrCl] <45 mL/min) or requiring dialysis would be excluded 4. Subjects with peripheral neuropathy ≥Grade 2