Essai Clinique

Généré le 16 mai 2025 à partir de

Titre	Étude de phase Ib/2 évaluant le sélinexor (KPT-330) en association avec des traitements de fond dans la prise en charge du myélome multiple réfractaire/résistant
Protocole ID	KCP-330-017 (STOMP)
ClinicalTrials.gov ID	NCT02343042
Type(s) de cancer	Myélome
Phase	Phase I-II
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	sélinexor
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	Québec
Investigateur principal	Dr Marc Lalancette
Coordonnateur	Diane Bernard 418-525-4444 poste 15782 Patricia Chabot 418-525-4444 poste 15769
Statut	Actif en recrutement
But étude	This study will independently assess the efficacy and safety of two combination therapies for the treatment of patients with relapsed/refractory multiple myeloma (RR MM): selinexor + dexamethasone + pomalidomide (SdP) and selinexor + dexamethasone + bortezomib (SdB).
Critères d'éligibilité	• Histologically confirmed diagnosis, measurable disease and evidence of disease progression of MM, as described below. • Symptomatic MM, based on IMWG guidelines. Patients must have measurable disease as defined by at least one of the following: • Serum M-protein ≥ 0.5 g/dL by serum electrophoresis (SPEP) or, for IgA myeloma, by quantitative IgA • Urinary M-protein excretion at least 200 mg/24 hours • Serum FLC ≥ 100 mg/L, provided that FLC ratio is abnormal • If serum protein electrophoresis is felt to be unreliable for routine M-protein measurement, then quantitative Ig levels by nephelometry or turbidometry are acceptable. • Any non-hematological toxicities (except for peripheral neuropathy as described in exclusion criterion #22) that patients experienced from treatments in previous clinical studies must have resolved to ≤ Grade 2 by Cycle 1 Day 1. • Adequate hepatic function within 21 days prior to C1 D1: • Adequate renal function within 21 days prior to C1 D1: • Adequate hematopoietic function within 21 days prior to C1 D1: SdP (Arm 1) Only: Relapsed and refractory MM with: • Documented evidence of PD after achieving at least SD for ≥ 1 cycle during a previous MM regimen (i.e., relapsed MM) • ≤ 25% response (i.e., patients never achieved ≥ MR) or PD during or within 60 days from the end of the most recent MM regimen (i.e., refractory MM)

	• Previously undergone ≥ 2 cycles of lenalidomide and a proteasome inhibitor (in separate therapeutic regimens [not for maintenance] or in combination) SdB (Arm 2) Only: Relapsed or refractory MM with: • Documented evidence of relapse after ≥ 1 previous line of therapy • Not refractory to bortezomib in their most recent line of therapy 9. SdL (Arm 3) Only: • Patients who received ≥ 1 prior therapeutic regimen (prior lenalidomide is allowed as long as patient was not refractory to prior lenalidomide)
Critères d'exclusion	• Smoldering MM. • MM that does not express M-protein or FLC (i.e., non-secretory MM is excluded), and quantitative immunoglobulin levels cannot be used instead • Documented active systemic amyloid light chain amyloidosis • Active MM involving the central nervous system (CNS) • Active plasma cell leukemia • Blood (or blood product) transfusions and blood growth factors within 7 days of C1 D1 only for patients enrolling into the Expansion Phase • Radiation, chemotherapy, or immunotherapy or any other anticancer therapy ≤ 2 weeks prior to C1 D1, and radio-immunotherapy within 6 weeks prior to C1 D1. Patients on long-term glucocorticoids during Screening, including use for spinal cord compression, do not require a washout period. Prior radiation is permitted for treatment of fractures or to prevent fractures as well as for pain management • Treatment with an investigational anti-cancer therapy within 3 weeks prior to C1 D1 • Prior autologous stem cell transplantation < 1 month, or allogeneic stem cell transplantation < 3 months prior to C1 D1 • Active graft versus host disease after allogeneic stem cell transplantation • A life expectancy of < 3 months • Major surgery within 4 weeks prior to C1 D1 • Active, unstable cardiovascular function: