Essai Clinique

Généré le 18 avr. 2024 à partir de

Titre	A Phase 2-3, Multicenter, Randomized, Double-blind Study of Selinexor (KPT-330) Versus Placebo in Patients With Advanced Unresectable Dedifferentiated Liposarcoma (DDLS)
Protocole ID	KCP-330-020
ClinicalTrials.gov ID	NCT02606461
Type(s) de cancer	Sarcome
Phase	Phase II-III
Type étude	Traitement
Médicament	Selinexor (KPT-330)
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Thierry Alcindor
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Statut	Fermé
But étude	This is a randomized, multicenter, double-blind, placebo-controlled, Phase 2-3 study of patients diagnosed with advanced unresectable dedifferentiated liposarcoma. Approximately 279 total patients will be randomized to study treatment (selinexor or placebo).
Critères d'éligibilité	• Patients ≥12 years of age • Body surface area (BSA) ≥ 1.2 m2 • Histologic evidence of DDLS at any time prior to randomization AND current evidence of DDLS requiring treatment • Must have measurable disease per RECIST v1.1 Response Criteria • Radiologic evidence of disease progression within 6 months prior to randomization. If the patient received other intervening therapy after documented disease progression, further disease progression must be documented after the completion of the intervening therapy • Must have had at least two (2) prior lines of systemic therapy for liposarcoma (not to exceed 5 prior lines) • If patient received any previous systemic therapy, the last dose must have been ≥ 21 days prior to randomization (or ≥ 5 half-lives of that drug - whichever is shorter) with all clinically significant therapy- related toxicities having resolved to less than or equal to Grade 1
Critères d'exclusion	• Patients with pure WDLS, myxoid/round cell or pleomorphic tumor histologic subtypes. • Known active Hepatitis B (HepB), Hepatitis C (HepC) or human immunodeficiency virus (HIV) infection. • Known central nervous system metastases