Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	A Randomized, Phase 2b Study of GC4711 in Combination With Stereotactic Body Radiation Therapy (SBRT) in the Treatment of Unresectable or Borderline Resectable Nonmetastatic Pancreatic Cancer
Protocole ID	GRECO-2
ClinicalTrials.gov ID	NCT04698915
Type(s) de cancer	Pancréas
Phase	Phase II
Type étude	Clinique
Médicament	GC4711 en association avec la radiothérapie stéréotaxique corporelle
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
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Statut	Actif en recrutement
But étude	GTI-4711-201 is designed as a Phase 2b, multicenter, randomized, double-blind, placebo-controlled study to determine the effect to OS by adding GC4711 to SBRT following chemotherapy in patients with unresectable or borderline resectable nonmetastatic
Critères d'éligibilité	• Histological or biopsy proven adenocarcinoma of the pancreas. Cytology is acceptable if histology cannot be obtained. • Newly diagnosed non-metastatic PC judged by tumor board to be feasible for SBRT • Completed at least 6 weeks of chemotherapy consisting of FOLFIRINOX, mFOLFIRINOX, or a gemcitabine-based doublet regimen prior to start of SBRT • Remain non-metastatic as confirmed by a CT scan at screening. • Female or male subjects ≥ 18 years of age • ECOG performance status of 0-2 • Adequate end-organ function
Critères d'exclusion	• Subjects with documented metastatic disease • First-line chemotherapy other than FOLFIRINOX, mFOLFIRINOX, and/or a gemcitabine-based doublet regimen • Prior abdominal RT with substantial overlap in radiation fields • Subjects not recovered/controlled from treatment-related toxicities • Uncontrolled malignancy other than PC • Uncontrolled gastric or duodenal ulcer disease within 30 days of dosing • Visible invasion of bulky tumor into the lumen of the bowel or stomach on endoscopy