Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	Étude de phase III randomisée à double aveugle comparant le Pembrolizumab Plus Gemcitabine/Cisplatin versus Placebo Plus Gemcitabine/Cisplatin en première ligne de traitement chez les participants avec carcinome des voies biliaires avancé et /ou non résécable
Protocole ID	MK-3475-966 (KEYNOTE-966)
ClinicalTrials.gov ID	NCT04003636
Type(s) de cancer	Pancréas
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Pembrolizumab + Gemcitabine/Cisplatine vs placebo + Gemcitabine/Cisplatine
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Jamil Asselah
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Statut	Fermé
But étude	This is a study of pembrolizumab plus gemcitabine/cisplatin versus placebo plus gemcitabine/cisplatin as first-line therapy in participants with advanced and/or unresectable biliary tract carcinoma. The study has 2 primary hypotheses: 1. Pembrolizumab plus gemcitabine/cisplatin is superior to placebo plus gemcitabine/cisplatin with respect to progression-free survival (PFS) per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 by blinded independent central review (BICR) and 2. Pembrolizumab plus gemcitabine/cisplatin is superior to placebo plus gemcitabine/cisplatin with respect to overall survival (OS).
Critères d'éligibilité	• Has histologically confirmed diagnosis of advanced (metastatic) and/or unresectable (locally advanced) biliary tract cancer (intra-or extrahepatic cholangiocarcinoma or gallbladder cancer). • Have measurable disease based on Response Evaluation Criteria in Solid Tumors (RECIST 1.1), as determined by the site investigator. • Participants with a history of hepatitis B or hepatitis C can be enrolled if they meet study criteria. • Provide archival tumor tissue sample or newly obtained core or excisional biopsy of a tumor lesion. • Have a life expectancy of greater than 3 months. • Have adequate organ function.
Critères d'exclusion	• Has had previous systemic therapy for advanced (metastatic) or unresectable (locally advanced) biliary tract cancer (intra-or extra hepatic cholangiocarcinoma or gallbladder cancer), with the exception of adjuvant therapy which is allowed. • Has ampullary cancer. • Has small cell cancer, neuroendocrine tumors, lymphoma, sarcoma and/or Mucinous cystic neoplasms. • Has received prior therapy with an anti-programmed cell death 1 (anti-PD-1), anti- programmed cell death ligand 1 or 2 (anti-PD-L1, anti-PD-L2) agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (e.g., CTLA-4, OX-40, CD137).

- Has a known history of, or any evidence of, central nervous system (CNS) metastases and/or carcinomatous meningitis, as assessed by local site investigator.
- Has had an allogenic tissue/solid organ transplant.