Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	A Phase 3, Open-Label, Randomized Study of Perioperative Dostarlimab Monotherapy Versus Standard of Care in Participants With Untreated T4N0 or Stage III dMMR/MSI-H Resectable Colon Cancer
Protocole ID	AZUR-2
ClinicalTrials.gov ID	NCT05855200
Type(s) de cancer	Côlon et rectum
Phase	Phase III
Type étude	Clinique
Médicament	Dostarlimab versus FOLFOX/CAPEOX
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL H SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Jamil Asselah
Coordonnateur	Ryan Liu 514-934-1934 poste 34905
Statut	Actif en recrutement
Date d'activation	07-08-2023
But étude	The primary purpose of this study is to evaluate the efficacy of perioperative dostarlimab compared with standard of care (SOC) in participants with untreated T4N0 or Stage III (resectable), defective mismatch repair/ microsatellite instability high (dMMR/MSI-H) colon cancer.
Critères d'éligibilité	• Has untreated pathologically confirmed colon adenocarcinoma • Has resectable colon adenocarcinoma defined as clinically T4N0 or Stage III • Has radiologically evaluable disease • Has a tumor demonstrating the presence of either dMMR status or MSI-H
Critères d'exclusion	• Has distant metastatic disease. • Has received prior medical therapy (chemotherapy, immunotherapy, biologic, or targeted therapy), radiation therapy or surgery for management of colon cancer • Has a tumor that, in the investigator's judgment is causing symptomatic bowel obstruction or otherwise requires urgent/emergent surgery • Has undergone any major surgical procedure, open biopsy, or experienced significant traumatic injury within 28 days prior to enrollment • Has any history of interstitial lung disease or pneumonitis • Has cirrhosis or current unstable liver or biliary disease per investigator assessment defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, esophageal/gastric varices, or persistent jaundice • Has a history of allogenic stem cell transplantation or organ transplantation • Is receiving any other anticancer or experimental therapy. No other experimental therapies (including but not limited to chemotherapy, radiation, hormonal treatment, antibody therapy, immunotherapy, gene therapy, vaccine therapy, or other experimental drugs) of any kind are permitted while the participant is receiving study intervention • Is pregnant, breastfeeding, or expecting to conceive children within the projected duration of the study

- Has a history of severe allergic and/or anaphylactic reactions to chimeric, human or humanized antibodies, fusion proteins, or known allergies to dostarlimab, or its excipients, or any components of FOLFOX or CAPEOX