Essai Clinique

Généré le 17 mai 2025 à partir de

Titre	A Proof-of-Concept Phase II Trial to Evaluate the EMT Inhibitor Sotevtamab Combined With FOLFOX Administered as Neoadjuvant Treatment Prior to Resection of Colorectal Cancer Liver Metastasis
Protocole ID	EGIA-003
ClinicalTrials.gov ID	NCT06225843
Type(s) de cancer	Colorectal
Phase	Phase II
Stade	Métastatique
Type étude	Clinique
Médicament	Sotevtamab avec FOLFOX
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dr Mustapha Tehfé
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Statut	Actif en recrutement
Date d'activation	15-02-2024
But étude	This is an open-label, single-arm, single-center proof-of-concept Phase II trial of sotevtamab in combination with FOLFOX-based preoperative neoadjuvant systemic chemotherapy in participants with resectable liver-dominant metastases and candidate to neoadjuvant FOLFOX followed by partial hepatectomy. Approximately 17 participants will be enrolled in this trial and will receive 4 cycles of FOLFOX (Cycle 1 to Cycle 4) as preoperative systemic chemotherapy and 6 cycles of sotevtamab (Cycle 1 to Cycle 6). One cycle of treatment will consist of 14 days (2 weeks). Sotevtamab will be administered by intravenous (IV) infusion at 800 mg on Day 1 and Day 8 of each cycle. FOLFOX will be administered on Day 1 of Cycle 1 to Cycle 4 as follows: oxaliplatin 85 mg/m² IV infusion + leucovorin 400 mg/m² IV infusion + 5-Fluorouracil (5-FU) 400 mg/m² IV bolus + 5-FU 2400 mg/m² continuous IV infusion over 46 hours. Participants will undergo liver metastasis resection with or without primary cancer resection following recovery from preoperative neoadjuvant systemic chemotherapy.
Critères d'éligibilité	• Participants (male or non-pregnant female) must be ≥ 18 years of age on the day of signing the informed consent. • Participants with stage IV colon or rectal adenocarcinoma with resectable liver-dominant metastases and candidate to neoadjuvant FOLFOX followed by partial hepatectomy. • Participants may have had resection of their primary colon or rectal adenocarcinoma in the past or will have their primary cancer resected at the same time as the liver metastases resection or after liver metastases resection. • Participants must not have received prior chemotherapy for metastatic disease. Prior adjuvant chemotherapy and radiotherapy following resection of primary tumor is acceptable if completed at least 12 months prior to trial enrolment. • For multiple liver metastases, participants may undergo liver metastases needle-ablation of some metastases combined with surgical resection of others, as long as at least one metastasis is surgically resected. • Participants with at least one measurable lesion according to RECIST 1.1. • Participants must have a liver metastasis amenable for biopsy with no contraindication for biopsy. • Participants must have an Eastern Cooperative Oncology Group (ECOG) performance status of

	≤ 2. • Participants must have recovered from the toxic effects resulting from the most recent cancer treatment to Grade 1 or less. If the participants underwent major surgery, they must have recovered from the complications and/or toxicity. • Participants must have a life expectancy of at least 3 months. • Participants must have adequate organ and immune function • Female participants of childbearing potential must have a negative serum pregnancy test within 72 hours prior to the first dose of trial treatment. • Participants (both male and female) of reproductive potential must be willing to practice highly effective methods of contraception throughout the trial and for up to 90 days after the last dose of trial medication. Abstinence is acceptable if this is the participant's usual lifestyle. • Female participants are not considered of childbearing potential if they have a history of surgical sterility or evidence of post-menopausal status defined as any of the following:i. ≥ 45 years of age and has not had menses for more than 2 yearsii. Amenorrheic for less than 2 years without hysterectomy and oophorectomy and a follicle stimulating hormone (FSH) value in the postmenopausal range at screeningii. Post hysterectomy, oophorectomy, or tubal ligation. Documented hysterectomy or oophorectomy must be confirmed with medical records of the actual procedure or by ultrasound. Tubal ligation must be confirmed with medical records of the actual procedure. • Participants must understand and be able and willing and likely to fully comply with the trial procedures, including scheduled follow-up, and restrictions. • Participants must have given written personally signed and dated informed consent to participate in the trial in accordance with the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, before completing any trial related procedures.
Critères d'exclusion	• Participants who have received prior therapy with sotevtamab • Concurrent administration of anti-VGFR, anti-EGFR, anti-VEGF or other biological or targeted therapy with neoadjuvant FOLFOX • Participants with MMR-deficient primary colorectal tumor • Hereditary colorectal cancer (e.g., familial colonic polyposis or Lynch syndrome) • Participants who have another malignancy that is progressing or requires active treatment. Exceptions include basal cell carcinoma of the skin, squamous cell carcinoma of the skin or in situ cervical cancer. • Participants who are expected to require any other form of systemic or localized antineoplastic therapy while on the trial. This includes maintenance therapy with another agent or radiation therapy. • Participants who are receiving a dose > 10 mg/day of prednisone (or equivalent) within 7 days prior to the first dose of study treatment or any other form of immunosuppressive medication. • Participants who are currently participating or have participated in a trial of an investigational agent or using an investigational device within 21 days of the first dose of trial treatment. The 21-day window should be calculated using the last dose of an investigational agent or last use of an investigational device. • Participants who have a pre-existing peripheral sensitive neuropathy with functional impairment. • Participants with clinically significant electrocardiogram (ECG) abnormalities. • Participants who have received or will receive a live vaccine with 30 days prior to the first dose of trial treatment. • Participants with a known history of human immunodeficiency (HIV). • Participants with an active Hepatitis B or C infection. • Participants with an active infection requiring antibiotic therapy. • Participants with a known history of alcohol or other substance abuse within the last year. • Participants with known hypersensitivity to FOLFOX. • Participants who have a history or current evidence of any condition, therapy or laboratory abnormalities that may confound the results of the trial, interfere with the participant's participation for the full duration of the trial or if it is not in the best interest of the participant to participate in the trial. • Participants with medical, social or psychosocial factors that, in the opinion of the treating Investigator, could impact the safety or compliance with trial procedures. • Participants who are pregnant or lactating or who are expecting to conceive or father children within the projected duration of the trial through 90 days after the last dose of sotevtamab or 180 days after the last dose of FOLFOX.