Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	Multicenter, Open-label, phase 2 Study of Carboplatin Plus Mirvetuximab Soravtansine Followed by Mirvetuximab Soravtansine Continuation in FR? Positive, Recurrent Platinum-sensitive, High-grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers Following 1 Prior Line of Platinum-based Chemotherapy
Protocole ID	IMGN853-0420
ClinicalTrials.gov ID	NCT05456685
Type(s) de cancer	Ovaire
Phase	Phase II
Type étude	Clinique
Médicament	Carboplatine + mirvetuximab soravtansine suivi de mirvetuximab soravtansine
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Diane Provencher
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Statut	Actif en recrutement
Date d'activation	18-07-2023
But étude	IMGN853-0420 is a multicenter, open-label, phase 2 study of carboplatin plus mirvetuximab soravtansine followed by mirvetuximab soravtansine continuation in folate receptor-alpha positive, recurrent platinum sensitive, high-grade epithelial ovarian, primary peritoneal, or fallopian tube cancer following 1 prior line of platinum-based chemotherapy.
Critères d'éligibilité	• Patients must be ≥ 18 years of age. • Patients must have an Eastern Cooperative Oncology Group Performance Status of 0 or 1. • Patients must have a confirmed diagnosis of high-grade serous epithelial ovarian, primary peritoneal, or fallopian tube cancer. • Patients must have relapsed after 1 prior line of platinum-based chemotherapy. • Patients must have platinum-sensitive disease defined as radiographic progression greater than 6 months from last dose of platinum-based chemotherapy. Note: Progression should be calculated from the date of the last administered dose of platinum therapy to the date of the radiographic imaging showing progression. • Prior BRCA testing on the tumor or prior germline testing is required for eligibility. If not done prior, tumor or germline testing will need to be done at study entry. Somatic and germline BRCA-positive patients must have received prior treatment with a PARPi. • Patients must have at least 1 lesion that meets the definition of measurable disease by RECIST v1.1 (radiologically measured by the investigator). • Patients must provide an archival tumor tissue block or slides, or undergo procedure to obtain a new biopsy using a low-risk, medically routine procedure for immunohistochemistry (IHC) confirmation of FRα positivity; FRα-expressing tumors will be defined and classified by the Ventana FOLR1 Assay into low, medium, and high expressions defined as 25%-49%, 50%-74%, and ≥ 75% of tumor cells with PS2+ staining intensity, respectively. Patients must have confirmation of FRα positivity of ≥ 25% of tumor staining at ≥ 2+ intensity for entry into the study. • Patients must have stabilized or recovered (Grade 1 or baseline) from all prior therapy-related toxicities (except alopecia) and have discontinued any maintenance therapy at least 4 weeks before the first dose of carboplatin plus MIRV.

	• Patients must have completed any major surgery at least 4 weeks before the first dose of carboplatin plus MIRV and have recovered or stabilized from the side effects of prior surgery before the first dose of carboplatin plus MIRV.
	• Patients must have adequate hematologic, liver, and kidney functions defined as:
	  • Absolute neutrophil count ≥ 1.5 × 109/L (1500/µL) without granulocyte colony-stimulating factor or long-acting white blood cell growth factors in the 10 days prior to the C1D1 dose
	  • Platelet count ≥ 100 × 109/L (100,000/µL) without platelet transfusion in the 10 days prior to the C1D1 dose
	  • Hemoglobin ≥ 9.0 g/dL without packed red blood cell transfusion in the 14 days prior to the C1D1 dose
	  • Serum creatinine ≤ 1.5 × ULN
	  • Aspartate aminotransferase and alanine aminotransferase ≤ 3.0 × ULN
	  • Serum bilirubin ≤ 1.5 × ULN (patients with documented diagnosis of Gilbert syndrome are eligible if total bilirubin < 3.0 × ULN)
	  • Serum albumin ≥ 2 g/dL
	• Patients must be willing and able to sign the informed consent form (ICF) and to adhere to the protocol requirements.
	• Females of childbearing potential (FCBP) must agree to use highly effective contraceptive method(s) while on study medication and for at least 3 months after the last dose of MIRV and 6 months after the last dose of carboplatin.
	• FCBP must have a negative pregnancy test within the 4 days prior to the C1D1 dose.

Critères d'exclusion	• Patients with endometrioid, clear cell, mucinous, or sarcomatous histology, mixed tumors containing any of the above types, or low-grade/borderline ovarian tumor
	• More than one line of prior chemotherapy. Lines of prior anticancer therapy are counted with the following considerations:
	  • Neoadjuvant ± adjuvant therapies are considered 1 line of therapy if the neoadjuvant and adjuvant correspond to 1 fully predefined regimen; otherwise, they are counted as 2 prior regimens.
	  • Maintenance therapy (eg, bevacizumab, PARPi) will be considered part of the preceding line of therapy (ie, not counted independently).
	• Patients with prior wide-field radiotherapy affecting at least 20% of the bone marrow
	• Patients with > Grade 1 peripheral neuropathy per Common Terminology Criteria for Adverse Events (CTCAE)
	• Patients with active or chronic corneal disorders, history of corneal transplantation, or active ocular conditions requiring ongoing treatment/monitoring, such as uncontrolled glaucoma, wet age-related macular degeneration requiring intravitreal injections, active diabetic retinopathy with macular edema, macular degeneration, presence of papilledema, or monocular vision
	• Patients with serious concurrent illness or clinically relevant active infection, including, but not limited to the following:
	  • Active hepatitis B or C infection (whether or not on active antiviral therapy)
	  • HIV infection
	  • Active cytomegalovirus infection
	  • Any other concurrent infectious disease requiring IV antibiotics within 2 weeks prior to the first dose of carboplatin plus MIRV Note: Testing at screening is not required for the above infections unless clinically indicated.
	• Patients with a history of multiple sclerosis or other demyelinating disease and/or Lambert-Eaton syndrome (paraneoplastic syndrome)
	• Patients with clinically significant cardiac disease including, but not limited to, any of the following:
	  • Myocardial infarction ≤ 6 months prior to first dose
	  • Unstable angina pectoris
	  • Uncontrolled congestive heart failure (New York Heart Association > class II)
	  • Uncontrolled ≥ Grade 3 hypertension (per CTCAE)
	  • Uncontrolled cardiac arrhythmias
	• Patients with a history of hemorrhagic or ischemic stroke within 6 months prior to enrollment
	• Patients with a history of cirrhotic liver disease (Child-Pugh Class B or C)
	• Patients with a previous clinical diagnosis of noninfectious interstitial lung disease, including noninfectious pneumonitis (exception: Grade 1 noninfectious pneumonitis diagnosed on or within 6 weeks after treatment with an immunotherapeutic agent used in the treatment of their malignancy that has resolved per investigator or resolution of the radiologic findings)
	• Patients requiring use of folate-containing supplements (eg, folate deficiency)
	• Patients with prior hypersensitivity to monoclonal antibodies (mAb)
	• Females who are pregnant or breastfeeding
	• Patients who received prior treatment with MIRV or other FRα-targeting agents
	• Patients with untreated or symptomatic central nervous system metastases
	• Patients with a history of other malignancy within 3 years before enrollment Note: patients with tumors with a negligible risk for metastasis or death (eg, adequately controlled basal-cell carcinoma or squamous-cell carcinoma of the skin, or carcinoma in situ of the cervix or breast) are eligible.
	• Prior known hypersensitivity reactions to study drugs or any of their excipients