Essai Clinique

Généré le 20 oct. 2020 à partir de

Titre	An Open-Label, Randomized, Phase 3 Clinical Trial of REGN2810 Versus Therapy of Investigator's Choice Chemotherapy in Recurrent or Metastatic Platinum-Refractory Cervical Carcinoma
Protocole ID	R2810-ONC-1676
ClinicalTrials.gov ID	NCT03257267
Type(s) de cancer	Col
Phase	Phase III
Stade	Métastatique
Type étude	Traitement
Médicament	Cemiplimab (REGN2810)
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	Montréal
Investigateur principal	Dre Susie Lau
Coordonnateur	Heather Gregory 514-340-8222 poste 24596
Statut	Fermé
But étude	The primary objective is to compare overall survival (OS) for patients with recurrent or metastatic platinum-refractory cervical cancer treated with either REGN2810 or investigator's choice (IC) chemotherapyThe secondary objectives are: • To compare progression-free survival (PFS) of REGN2810 versus IC chemotherapy • To compare overall response rate (ORR) (partial response [PR] + complete response [CR]) of REGN2810 versus IC chemotherapy per Response Evaluation Criteria in Solid Tumors 1.1 • To compare the duration of response (DOR) of REGN2810 versus IC chemotherapy • To compare the safety profiles of REGN2810 versus IC chemotherapy by describing adverse events (AE) • To compare quality of life (QOL) for patients treated with REGN2810 versus IC chemotherapy using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30)
Critères d'éligibilité	Key Inclusion Criteria: • Recurrent, persistent, and/or metastatic cervical cancer, for which there is not a curative intent option (surgery or radiation therapy with or without chemotherapy). Acceptable histologies are squamous carcinoma, adenocarcinoma, and adenosquamous carcinoma. Sarcomas and neuro-endocrine carcinomas are not eligible histologies. • Tumor progression or recurrence within 6 months of last dose of platinum therapy that was used to treat metastatic, persistent or recurrent cervical cancer • Patient must have measurable disease as defined by RECIST 1.1. • Eastern Cooperative Oncology Group (ECOG) performance status ≤1 • ≥18 years old • Adequate organ or bone marrow function • Received prior bevacizumab therapy or had clinically documented reason why not administered • Received prior paclitaxel therapy or had clinically documented reason why not administered

Critères d'exclusion	Key Exclusion Criteria: • Ongoing or recent (within 5 years) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments • Prior treatment with an agent that blocks the PD-1/PD-L1 pathway • Prior treatment with systemic immune modulating agents (other than anti-PD-1/PD-L1 agents) that was within 28 days prior to enrollment, or within 90 days prior to enrollment if there was an immune related adverse event, or associated with toxicity that resulted in discontinuation of the immune modulating agent • Active or untreated brain metastases • Immunosuppressive corticosteroid doses (>10 mg prednisone daily or equivalent) within 4 weeks prior to the first dose of REGN2810 • Active infection requiring therapy • History of pneumonitis within the last 5 years • Documented allergic or acute hypersensitivity reaction attributed to antibody treatments • Known allergy to doxycycline or other tetracycline antibiotics • Concurrent history of malignancy other than cervical cancer within 3 years of first planned dose of REGN2810, except for tumors with negligible risk of metastasis