Essai Clinique

Généré le 28 janv. 2022 à partir de

Titre	Étude de phase II ouverte et multicentrique évaluant un traitement immunothérapeutique, DPX-Survivac, en association avec le cyclophosphamide à faible dose et le pembrolizumab, chez des sujets présentant certaines tumeurs solides avancées et récurrentes.
Protocole ID	P1719-SUR-Z11 / KEYNOTE 903
ClinicalTrials.gov ID	NCT03836352
Type(s) de cancer	Tumeurs solides
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	DPX-Survivac avec Low Dose Cyclophosphamide et Pembrolizumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	Québec
Investigateur principal	Dr Vincent Castonguay
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Statut	Actif en recrutement
But étude	This study will assess the safety and efficacy of DPX-Survivac and low dose cyclophosphamide with pembrolizumab in subjects with selected advanced and recurrent solid tumours.
Critères d'éligibilité	• Subjects with advanced or metastatic solid tumours who have disease progression • Epithelial ovarian, fallopian tube, or peritoneal cancer • Hepatocellular carcinoma • Non-small cell lung cancer • Urothelial cancer • Microsatellite instability high solid tumours, other than the above indications • Radiologic and/or biochemical evidence of disease progression • Completion of pre-treatment tumour biopsy • Subjects with HCC, NSCLC, BICa, or MSI-H subjects other than those with gastric or colorectal cancer must have evidence of survivin expression in their pre-treatment biopsy sample • Must have measurable disease by RECIST v1.1 • Ambulatory with an ECOG 0-1 • Life expectancy ≥ 6 months • Meet protocol-specified laboratory requirements
Critères d'exclusion	• Eligible for otherwise curative treatment or undergoing concurrent therapy • Prior therapy with an anti-PD-1, anti-PD-L1, or anti PD L2 agent or with an agent directed to another stimulatory or co-inhibitory T cell receptor where subject was discontinued from that treatment due to a Grade 3 or higher immune-related toxicity • Prior receipt of survivin-based vaccine(s) and/or immunotherapies • Concurrent second malignancy other than non-melanoma skin cancer, cervical carcinoma in situ, or controlled bladder cancer • Clinical ascites or metastatic pleural fluid • Malignant bowel obstruction or recent history of bowel obstruction

- For OvCa, subjects with any single lesion greater than 5 cm
- Autoimmune disease requiring treatment within the last two years (except replacement therapy)
- Recent history of thyroiditis
- Any history of (non-infectious) pneumonitis that required steroid therapy or current pneumonitis
- Presence of a serious acute or chronic infection
- Active CNS metastases and/or carcinomatous meningitis
- GI condition that might limit absorption of oral agents
- Allogenic tissue/solid organ transplant
- Other serious intercurrent chronic or acute illness, including myocardial infarction or cerebrovascular event within 6 months
- Ongoing treatment with steroid therapy or other immunosuppressive
- Receipt of live attenuated vaccines
- Acute or chronic skin and/or microvascular disorders
- Edema or lymphedema in the lower limbs > grade 2
- Severe hypersensitivity (≥ Grade 3) to pembrolizumab