Essai Clinique

Généré le 27 avr. 2024 à partir de

Titre	Étude multicentrique en 2 étapes de phase IB/II, menée sans insu, visant à déterminer l'efficacité et l'innocuité du durvalumab (MEDI4736) et du paclitaxel, administrés ensemble ou en association avec de nouveaux médicaments oncologiques, pour le traitement de première intention du cancer du sein triple négatif métastatique
Protocole ID	BEGONIA
ClinicalTrials.gov ID	NCT03742102
Type(s) de cancer	Sein
Phase	Phase I-II
Stade	Métastatique
Type étude	Traitement
Institution	CISSS DE LA MONTEREGIE-CENTRE HOPITAL CHARLES-LE MOYNE 3120 boulevard Taschereau, Greenfield Park, QC, J4V2H1
Ville	Greenfield Park
Investigateur principal	Dre Catherine Prady
Coordonnateur	Stéphanie Bonin 450-466-5000 poste 7691
Statut	Fermé
But étude	This is a Phase IB/II, 2-stage, open-label, multicenter study to determine the efficacy and safety of durvalumab + paclitaxel + novel oncology therapies (i.e. therapies designed for immune modulation) and durvalumab + paclitaxel alone as first-line treatment in patients with metastatic triple negative breast cancer (TNBC). The study is designed to concurrently evaluate potential novel triplet combinations with clinical promise using a 2-stage approach. Part 1 is a Phase IB study of safety and initial efficacy, and Part 2 is a Phase II study. The triplet treatment regimens evaluated in Part 2 will depend on the evaluation of safety and efficacy outcomes in Part 1.
Critères d'éligibilité	• Female • At least 18 years of age at the time of screening • Patient must have locally confirmed TNBC • No prior treatment for metastatic (Stage IV) TNBC • Patient must have at least 1 lesion, not previously irradiated, that can be accurately measured • WHO/ECOG status at 0 or 1 at enrollment
Critères d'exclusion	• History of venous thromboembolism in the past 3 months • Diagnosis of diabetes mellitus Type I or diabetes mellitus Type II requiring insulin treatment • History of allogeneic organ transplantation • Active or prior documented autoimmune or inflammatory disorders • Active infection including tuberculosis, hepatitis B (known positive HBV surface antigen [HBsAg] result), hepatitis C virus (HCV), or human immunodeficiency virus (positive HIV 1/2 antibodies) • Untreated CNS metastases • Known allergy or hypersensitivity to any of the study drugs or any of the study drug excipients • Any concurrent chemotherapy, IP, or biologic therapy for cancer treatment • Female patients who are pregnant or breastfeeding