Essai Clinique

Généré le 14 mai 2024 à partir de

Titre	Étude ouverte de phase II comprenant un seul groupe, visant à évaluer le dostarlimab en monothérapie chez des patients atteints d'un cancer du rectum localement avancé, de stade II/III, dMMR/MSI-H qui n'a pas été traité auparavant
Protocole ID	GSK-219369 (AZUR1)
ClinicalTrials.gov ID	NCT05723562
Type(s) de cancer	Côlon et rectum
Phase	Phase II
Stade	Localement avancé
Type étude	Clinique
Médicament	Dostarlimab
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
Investigateur principal	Dr Frédéric Lemay
Coordonnateur	Michelle Roy 819-346-1110 poste 12848
Statut	Actif en recrutement
Date d'activation	25-08-2023
But étude	Estimer l'efficacité du dostarlimab chez les participants atteints d'un cancer du rectum dMMR/MSI-H de stade II/III (localement avancé) qui n'a pas été traité auparavant.
Critères d'éligibilité	• Participant has histologically confirmed Stage II to III (T3-T4, N0, or T any, N+), locally advanced rectal cancer • Participant has radiologically and endoscopically evaluable disease. • Participant has a tumor which can be categorized as dMMR or MSI-H by local or central assessment
Critères d'exclusion	• Participant has distant metastatic disease. • Participant has received prior radiation therapy, systemic therapy, or surgery for management of rectal cancer. • Participant has any history of interstitial lung disease or pneumonitis • Participant has experienced any of the following with prior immunotherapy: any irAE of Grade ≥3, immune-related severe neurologic events of any grade (e.g., myasthenic syndrome/myasthenia gravis, encephalitis, Guillain Barré Syndrome, or transverse myelitis), exfoliative dermatitis of any grade (Stevens-Johnson Syndrome, toxic epidermal necrolysis, or DRESS syndrome), or myocarditis of any grade. Non clinically significant laboratory abnormalities are not exclusionary. • Participant has a known additional malignancy that progressed or required active treatment within the past 2 years. Exceptions include adequately treated superficial skin cancers, superficial bladder cancers, and other in situ cancers. • Participant has an active autoimmune disease that has required systemic treatment in the past 2 years (i.e., with use of disease-modifying agents, corticosteroids, or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement

therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment.
- Participant has a history of severe allergic and/or anaphylactic reactions to chimeric, human or humanized antibodies, fusion proteins, or has known allergies to dostarlimab or its excipients.