MK3475-866 / Keynote-866 - MK3475-866 / Keynote-866 (dernière mise à jour : 22/11/2019)

http://archimaid.fr/index.php?action=show&id=971

Informations générales

Titre de l'étude : Etude de phase III, randomisée, en double-aveugle évaluant l'administration périopératoire du pembrolizumab (Mk-3475) + chimiothérapie néoadjuvante versus placebo périopératoire + chimiothérapie néoadjuvante chez des patients éligible au cisplatine atteins de cancer de la vessie envahissant le muscle (Keynote-866)

Traitement : Néoadjuvant / Adjuvant / Chirurgie

Type d'étude : Hors ciblage moléculaire

Phase : II/III **Stade** : Localisé à Localement avancé **Ligne(s)** : 1

Schéma : A global study to evaluate peri-operative pembrolizumab with chemotherapy versus placebo to pembrolizumab plus chemotherapy in cisplatin eligible patients.

Spécialités / Localisations

Spécialité n°1 : Voies urinaires

CIM10 - Localisation n°1 : **C67** - Tumeur maligne de la vessie

Critères

Critères d'inclusion : - Have a histologically confirmed diagnosis of muscle invasive bladder cancer (T2-T4aN0M0) with predominant (>=50%) urothelial histology (histology and presence of muscle invasion to be confirmed by BICR): Participants with mixed histology are eligible provided the urothelial component is >=50%.

Participants whose tumors contain any neuroendocrine component are not eligible.

Urothelial carcinomas not originating from the bladder (e.g., upper tract [ureters, renal pelvis], urethra) are not eligible.

Have clinically non-metastatic bladder cancer (N0M0) determined by imaging (computed tomography (CT) chest or magnetic resonance imaging (MRI) of the abdomen/pelvis.
Be deemed eligible for RC + PLND by his/her urologist and/or oncologist and agree to undergo curative intent standard RC + PLND (including prostatectomy if applicable).
Have a transurethral resection (TUR) of a bladder tumor that is submitted and adequate to determine histology, muscle invasion, and PD-L1 status by central pathology vendor.
Have Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
Have demonstrated adequate organ function.

Critères de non-inclusion :
Has a known additional malignancy that is progressing or has required active anti-cancer treatment <=3 years of study randomization with certain exceptions.
Has received any prior systemic anti-neoplastic treatment for MIBC.

Is cisplatin-ineligible, as defined by meeting any one of the study criteria.
Has received 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 (e.g., CTLA-4, OX-40, CD137).
Has received therapy with hematopoietic growth factor such as granulocyte-colony stimulating factor (G-CSF) or granulocyte-monocyte-colony stimulating factor(GM-CSF) in 14 days prior to randomization.
Has received prior systemic anti-cancer therapy including investigational agents within 3 years of randomization.
Has received any prior radiotherapy to the bladder.
Has received a live vaccine within 30 days prior to the first dose of study drug.
Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study intervention.
Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior the first dose of study drug.
Has hypersensitivity to monoclonal antibodies (mAbs, including pembrolizumab) and/or any of their excipients.
Has severe hypersensitivity (>=Grade 3) to cisplatin and/or gemcitabine and any of their excipients.
Has an active autoimmune disease that has required systemic treatment in past 2 years
Has a history of (non-infectious) pneumonitis that required steroids or has current pneumonitis.
Has an active infection requiring systemic therapy.

Informations promoteur

Nom du promoteur : MSD (Merck Sharp & Dohme Corp.)

Type de promoteur : Industriel

Adresse : - 00000 HORS FRANCE

Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : Centre François BACLESSE

Adresse : 3 avenue du Général Harris 14000 CAEN

Investigateur : Florence JOLY

TEC / ARC / IDE : Astrid LETIEMBRE - *Mail :* a.letiembre@baclesse.unicancer.fr - *Tél :*

Ouverture de l'essai : OUVERT

Liens utiles

Clinical Trials : https://clinicaltrials.gov/ct2/show/study/NCT03924856?cond=keynote-866&draw=2&rank=1