GARNET - Cohorte F – Les patients atteints de tumeur solide récurrente ou avancée à MSI-H ou de tumeur solide POLE-mut, à l'exception des cancers de l'endomètre (dernière mise à jour : 19/09/2019)

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Informations générales

Titre de l'étude : Étude de phase 1 avec escalade de dose et cohorte d'expansion, portant sur le TSR-042, un anticorps monoclonal anti-PD-1 chez des patients atteints de tumeurs solides à un stade avancé

Traitement : Métastasique ou localement avancé

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

Phase : I **Stade** : Localement avancé à Métastasique **Ligne(s)** : 3, 4, X

Schéma : This is a multicenter, open-label, first-in-human Phase 1 study evaluating the anti-programmed death receptor 1 (anti-PD-1) antibody TSR-042 in patients with advanced solid tumors who have limited available treatment options. The study will be conducted in 2 parts: dose escalation and cohort expansion. The cohort expansion may include various tumor types, including endometrial, Non-Small Cell Lung cancer, and MSI-H solid tumors.

Part 1 - Dose Escalation
Part 2 of the study will be conducted in two subparts:
In Part 2A, safety and tolerability of TSR-042 at fixed dose will be evaluated.
In Part 2B, clinical activity of TSR-042 will be evaluated.
Intervention: Biological: TSR-042

Spécialités / Localisations

Spécialité n°1 : Toutes tumeurs solides

CIM10 - Localisation n°1 : **C** - Toutes localisations

Critères

Critères d'inclusion : - Patient is at least 18 years of age
- Patient with advanced or metastatic solid tumor and has disease progression after treatment who are intolerant to treatment that meets the following requirements for the part of the study they will participate in:
1. Part 1: Patient with any advanced or metastatic solid tumor
2. Part 2A: Patient with any advanced or metastatic solid tumor
3. Part 2B: Patient with Non-Small Cell Lung Cancer (NSCLC), Endometrial cancers, and MSI-H solid tumors.
- Female patients, if of childbearing potential, must have a negative serum pregnancy test within 72 hours prior to the date of the first dose of study medication.
- Female patients of childbearing potential must agree to use 2 adequate methods of contraception with their partner starting with the screening visit through 150 days after the last dose of study therapy.
- Eastern Cooperative Oncology Group (ECOG) performance status of <= 2 for Part 1 and <= 1 for Part 2. Adequate organ function.

Critères de non-inclusion : - Patient has received prior therapy with an anti- programmed death receptor 1 (anti-PD-1), anti-PD-1- ligand-1 (anti-PD-L1), or anti-PD-1 ligand-2 (anti-PD- L2) agent.
- Known uncontrolled central nervous system (CNS) metastases and/or carcinomatous meningitis. Note: Patients with previously treated brain metastases may participate provided they are stable (without evidence of progression by imaging for at least 4 weeks prior to the first dose of study treatment and any neurologic symptoms have returned to baseline), have no evidence of new or enlarging brain metastases, and are clinically stable off steroids for at least 7 days prior to study treatment. Carcinomatous meningitis precludes a patient from study participation regardless of clinical stability.
- Known additional malignancy that progressed or required active treatment within the last 2 years. Exceptions include basal cell carcinoma of the skin, squamous cell cancer (SqCC) of the skin that has undergone potentially curative therapy, or in situ cervical cancer.
- Known history of human immunodeficiency virus (HIV) (HIV 1/2 antibodies).
- Known active hepatitis B (eg, hepatitis B surface antigen [HBsAg] reactive) or hepatitis C (eg, hepatitis C virus ribonucleic acid (HCV RNA) (qualitative) is detected).
- Active autoimmune disease that has required systemic treatment in the past 2 years (ie, with use of disease- modifying agents, corticosteroids, or immunosuppressive drugs). Replacement therapy (eg, thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment.
- History of interstitial lung disease.

Informations promoteur

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials : https://clinicaltrials.gov/ct2/show/NCT02715284